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No. 08-____

IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY,
Petitioner,

v.

STAR SCIENTIFIC, INC.,
Respondent.

*On Petition for a Writ of Certiorari to the United
States Court of Appeals for the Federal Circuit*

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Federal Circuit in this case reversed a district court ruling that two patents were unenforceable due to inequitable conduct. It thus overturned as clearly erroneous district court findings made after a week-long trial, which relied expressly on credibility findings. The district court found that the applicant, Jonnie Williams, had made affirmative misstatements to the Patent Office—which the Federal Circuit acknowledged—and never over several years disclosed known prior art that the district court ruled, and the Federal Circuit did not dispute, was highly material. The district court expressly found that this pattern of conduct demonstrated intent to deceive the Patent Examiner.

In reversing, the Federal Circuit substantially ignored this reasoning, and focused instead on a single incident that was peripheral to the district court's analysis. The court below never mentioned the district court's finding that the prolonged non-disclosure of known highly material information showed an intent to deceive and, contrary to its own precedents, strongly suggested that the materiality of concealed information should not be considered in assessing intent for purposes of inequitable conduct.

The Question Presented is whether the decision below unduly narrows the duty of candor owed by a patent applicant to the Patent Office and violates fundamental principles of appellate review of trial court fact-finding.

**PARTIES TO THE PROCEEDING
AND CORPORATE DISCLOSURE STATEMENT**

The parties to the proceeding below were Petitioner R.J. Reynolds Tobacco Company (a North Carolina Corporation), R.J. Reynolds Tobacco Company (a New Jersey Corporation), and Star Scientific, Inc., the Respondent. R.J. Reynolds Tobacco Company (a North Carolina Corporation) is successor by merger of R.J. Reynolds Tobacco Company (a New Jersey Corporation), which ceased to exist as of July 30, 2004.

Petitioner R.J. Reynolds Tobacco Company is directly and wholly owned by R.J. Reynolds Tobacco Holdings, Inc. (a Delaware Corporation). R.J. Reynolds Tobacco Holdings, Inc. is an indirect wholly-owned subsidiary of Reynolds American, Inc., a publicly traded corporation. Brown & Williamson Holdings, Inc. owns more than 10% of the common stock of Reynolds American, Inc. and is an indirect, wholly-owned subsidiary of British American Tobacco, plc., a publicly traded corporation.

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PETITION FOR A WRIT OF CERTIORARI

R.J. Reynolds Tobacco Company ("Reynolds") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is reported at 537 F.3d 1357. The district court's decision finding the patents-in-suit unenforceable based on inequitable conduct (Pet. App. 31a) and its opinion granting summary judgment for Reynolds based on indefiniteness (Pet. App. 77a) are unreported.

JURISDICTION

The district court had jurisdiction over Respondent's claims under 28 U.S.C. §§ 1331 and 1338(a). The Court of Appeals had jurisdiction to review the district court's final judgment under 28 U.S.C. § 1295(a)(1). The United States Court of Appeals for the Federal Circuit entered its judgment and opinion on August 25, 2008, and denied Reynolds's petition for rehearing or rehearing *en banc* on October 22, 2008. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 282 of 35 U.S.C. provides, in relevant part:

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) Noninfringement, absence of liability for infringement or unenforceability.

STATEMENT

A. Legal Framework

The Patent Clause of the Constitution authorizes the Congress "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." Art. I, § 8, cl. 8. It "is both a grant of power and a limitation." *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966). Congress may neither "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby," nor "authorize the issuance of patents whose effects are to remove existent knowledge from the public domain." *Id.* at 6.

The primary responsibility for drawing this constitutional distinction between patentable and "unpatentable material lies in the Patent Office," and it is "a most difficult task." *Id.* at 18. Those pursuing applications before the Patent and Trademark Office ("PTO") must act with the "highest degree of candor and good faith," so that the Office can "rely upon their integrity and deal with them in a spirit of trust and confidence." *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949). Patent applicants and their representatives "have an uncompromising duty to report to [the PTO] all facts concerning possible fraud or inequity underlying the applications in issue." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818 (1945).

The inequitable conduct doctrine is a principal way the duty of candor is enforced. Inequitable conduct exists where clear and convincing evidence shows that the applicant withheld or misstated information in its submissions to the PTO, that information was

“material” to patentability,¹ and the misstatement or omission was made with “intent to deceive” the PTO. *Dayco Prods., Inc. v. Total Containment, Inc.* 329 F.3d 1358, 1362-63 (Fed. Cir. 2003). Where material information has thus been intentionally misstated or withheld, a court must “weigh[] . . . the materiality and intent in light of all the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable.” *Id.* (internal quotation marks and emphasis omitted).

B. Facts

This petition arises from a suit brought by Respondent Star Scientific, Inc. (“Star”) against Reynolds, alleging infringement of two patents, United States Patents No. 6,202,649 (the “649 patent”) and No. 6,425,401 (the “401 patent”). Pet. App. 32a. Jonnie Williams is the named inventor of both patents. App. A281-82.²

¹ Information is material to patentability when it is not cumulative, and “(1) [i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) [i]t refutes, or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the Office, or (ii) [a]sserting an argument of patentability.” 37 C.F.R. § 1.56(b) (2000) (“Rule 56”).

Before 1992 the test was formulated as whether there was a substantial likelihood that a reasonable examiner would consider it important. 37 C.F.R. § 1.56(a) (1991). The Federal Circuit has held that the 1992 rule change to “an arguably narrower standard of materiality does not supplant or replace our case law. Rather, it merely provides an additional test of materiality.” *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

² App. A __ refers to the Federal Circuit Appendix. Star brought suit on the ‘649 patent on May 23, 2001, while the ‘401 patent

The patents relate to methods for treating tobacco plants to purportedly prevent formation of chemicals called tobacco specific nitrosamines ("TSNAs"). Pet. App. 33a-35a. These TSNAs, which may be carcinogenic, can form in the tobacco plants during the curing process, and the tobacco industry has looked for curing techniques that minimize or eliminate their formation. *Id.* at 34a-35a.

There are several ways to cure tobacco. The oldest, "air curing," simply relies on the exposure of tobacco leaves to untreated air to dry and cure them. Pet. App. at 34a. To accelerate the curing process, heated air is commonly used in several ways. In "radiant heat indirect-fired curing," *id.* at 3a, (sometimes called "flue-curing"), pipes conduct heated air through a curing barn and the exhaust from the burned fuel is discharged outside. Roughly since the 1970s, in the United States, it has become much more common to pack the tobacco more closely together and blow hot air through it ("bulk-curing" methods). One method, "forced air indirect-fired curing," blows air warmed by a heat exchanger into the curing barn with a fan, and the resultant exhaust is expelled outside the barn. *Id.* Another method—the most popular one in recent decades—is "direct-fired curing," where heated air produced by combustion of clean-burning fuels like propane is

application was still pending. On July 30, 2002, the same day that the '401 patent issued, Star brought a second lawsuit alleging violation of that patent, and the two cases were merged for trial. Pet. App. 31a-32a.

blown through the curing barn, thus exposing the tobacco to exhaust gases during curing. *Id.*

The patents-in-suit claim curing methods applied to prevent the formation of TSNA's during curing. The patents theorize that TSNA's form "by the action of the micro flora on the surface of the leaf under anaerobic conditions," which can be greatly curtailed or stopped by controlling certain conditions, including "humidity, rate of temperature change, temperature, the time of treatment of the tobacco, the airflow (through the curing apparatus or barn), CO level, CO₂ level, O₂ level, and the arrangement of the tobacco leaves." App. A5837 (col. 1, ll. 57-59), A5838 (col. 4, ll. 25-29). The '649 patent pertains to tobacco generally, while the '401 patent applies specifically to Virginia flue-cured tobacco. *See, e.g.*, App. A5846 (col. 20, ll. 4-14) and A6022 (col. 20, ll. 8-19).

After a seven-day bench trial regarding Reynolds' inequitable conduct defense, the district court held both patents unenforceable. It held that "Williams and others kept critical information from the PTO so as to give the false impression that . . . there had been no curing processes used in the United States . . . capable of producing tobacco with low levels of TSNA." Pet. App. 71a, 31a-76a.

Evidence of low TSNA levels being achieved by longstanding curing methods, without employing applicant's techniques, bears on whether the patents identify a patentable innovation. 35 U.S.C. § 102. Some such evidence is summarized in a letter, dated August 28, 1998, prepared for Star's patent counsel by Star's technical consultant, Dr. Harold Burton, on the direct request of inventor Jonnie Williams, App. A281-82:

I was in China for two weeks during 1997 and I was given commercial Chinese cigarettes. . . . *To my surprise I could not detect TSNA or when I did they were very low. . . . Since China is a developing country, they are still us[ing] the old curing technology that was abandoned in the US during the sixties. It seemed to me that the probable cause for the absence of TSNA was their use of the old flue-curing techniques.*

App. A6238 (emphasis added); *see also* Pet. App. 47a-49a.

Dr. Burton testified that he told Williams that he “had analyzed cigarettes from China” and found that “they were low in nitrosamines.” App. A523; *see also* App. A288 (Williams testimony). And Williams acknowledged knowing, “by September 15, 1998,” that the existing indirect fire curing barns could produce low TSNA tobacco, indeed sometimes tobacco “as low as [he was] endeavor[ing] to claim with [his] own invention.” App. A290.

Williams’ first patent counsel, Romulo Delmendo, likewise discussed with Williams “the Chinese commercial cigarettes and also the radiant curing process,” while trying to understand what the TSNA levels in U.S. tobacco would be if you “just heated [the tobacco] up” without the controls reflected in the patent. App. A216. Williams told Delmendo that, in that circumstance, “you’ll get high TSNA levels.” App. A289 (Williams testimony); A217 (Delmendo testimony).

Based on that information, the provisional application which led to the ‘649 patent, filed on September 15, 1998, contained the concededly false state-

ment, Pet. App. 17a n.7, that flue-curing practiced in China and other countries—where “radiant heat emanating from the flue pipes is used to cure the tobacco leaves . . . *has been determined . . . [when] applied to tobacco grown in the United States [to] yield[] tobacco products with high levels of TSNA.*” See Pet. App. 49a-50a; App. A290. “[G]reat portions of the [Burton] letter” were included in the provisional application. App. A82. The language of the letter reporting “the TSNA results for the Chinese commercial cigarettes” was almost the only part of the letter omitted. App. A225.

After filing the provisional application, Williams personally visited a farm in Virginia and secured samples of tobacco cured using another prior art method—forced air indirect-fired curing—coupled with microwave at the end of the process—and, after testing, learned that “very low” TSNA levels had been achieved. App. A292. (“Curran data.”) Williams withheld that data both from the PTO and from his patent counsel Delmendo. App. A292 (Williams testimony); App. A216 (Delmendo testimony); Pet. App. 6a. This occurred at a time when Delmendo “had concerns about whether the information in the Burton letter should be disclosed to the PTO.” Pet. App. 20a, 51a-52a; App. A219-20.

The non-provisional (“final”) ‘649 application that was filed on September 15, 1999 also failed to disclose the Burton letter, the Curran data, or, more generally, the fact that low TSNA levels had been produced using longstanding curing methods, without using applicant’s claimed innovation. The provisional application’s false statement regarding radiant heat curing was omitted from the final application, which instead acknowledged that the method is

still used commercially outside the United States, in China and elsewhere, App. A5837 (col. 2, ll. 54-60), but said nothing about the TSNA levels produced using that method.

After filing the final '649 application, Williams and Star changed legal counsel. Star's initial counsel, Delmendo, who had concerns about whether the Burton letter should be disclosed, Pet. App. 20a, was replaced by Paul Rivard and the firm of Banner & Witcoff. Pet. App. 7a, 54a. The files were transferred to Banner & Witcoff through an intermediary attorney from a third law firm. *Id.* Rivard testified that neither Williams nor their predecessor counsel called the Burton letter or the Curran data to his attention. App. A228-29.

Thereafter, on February 15, 2000, Star's new counsel filed a "Petition to Make Special" to accelerate the processing of the '649 application. App. A10327-40. Notwithstanding the heightened disclosure obligations under such a petition,³ and even though Rivard asked Williams to provide relevant information about the prior art, Williams did not provide him with the Burton letter, the Curran data, or the essential fact that low TSNA levels had been produced with conventional curing methods. App. A228 (Rivard testimony); App. A294 (Williams

³ A Petition to Make Special requires the applicant to certify "that the applicant or assignee has made or caused to be made a careful and thorough search of the prior art, or has good knowledge of the pertinent prior art." Manual of Patent Examining Procedure ("MPEP") § 708.02. Such a petition requires "an extra effort to look for and produce all relevant prior art." *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994) (emphasis omitted).

testimony).

Williams had another opportunity to disclose the withheld information at an interview with the patent examiner in August 2000, but again failed to do so. App. A295-296 (Williams testimony); App. A234 (Rivard testimony). Indeed, at no point before the issuance of the '649 patent on March 20, 2001 did Williams or his lawyers share with the PTO the Burton letter, the Curran data, or the fact that conventional curing methods had produced low TSNA tobacco. *See* Pet. App. 4a-7a.

Eleven days after the PTO allowed the '649 patent on September 14, 2000, Williams filed the continuation application that led to the '401 patent.⁴ Again, Star's lawyers filed a Petition to Make Special that expedited the examination of the '401 patent, and at that time again failed to disclose the relevant prior art. App. A10327-40. Nor was that information ever disclosed to the PTO during the '401 patent prosecution.

The '401 patent application had been pending nearly seventeen months when the Burton letter came to the attention of Star's trial counsel. App. A275 (Attorney McMillan testified he had read the Burton letter by February 11, 2002). Following its allowance, on June 10, 2002 trial counsel brought it to the attention of Star's patent counsel, Rivard, *id.*, who immediately drafted a supplemental information disclosure statement including the Burton letter and the Curran data, and circulated it among four

⁴ In a continuation application, applicant seeks a new "child" patent (here, the '401) with an identical specification but different claims than the "parent" patent (here, the '649).

Star lawyers. Star's trial counsel and patent counsel from the Banner firm discussed whether the information contained in the Burton letter should be disclosed to the PTO, and all but one (who said that others should decide) agreed that it should be. Pet. App. 66a-68a. Nonetheless, the information was never disclosed. App. A240, A253-54. The '401 patent issued on July 30, 2002.

C. The District Court's Inequitable Conduct Decision

In a 47-page opinion, the district court ruled that both patents-in-suit were unenforceable based on inequitable conduct. Pet. App. 31a-76a.⁵ The district court concluded that "Williams and others deliberately misled the PTO in a material manner by keeping from the PTO the critical fact known to Williams and others that the claimed beneficial result—tobacco with low to undetectable TSNA levels—*had been achieved in the United States* prior to the application that led to the Patents-in-Suit." *Id.* at 43a (emphasis in original). In its "Inequitable Conduct Determination" at the end of its opinion, the district court first stated:⁶

Even if one could argue that the Burton Letter *per se* need not have been disclosed, the

⁵ In a previous order addressing many of the same facts, the trial court had ordered disclosure of certain documents over Star's attorney-client privilege claims, based on the crime/fraud exception. Pet. App. 90a.

⁶ The district court noted several times that certain of its conclusions rested in part on assessments of witness credibility. Pet. App. 54a-55a, 59a-60a, 69a-70a. The district court also included a section in its decision addressing "Particular Credibility Concerns." *Id.* at 68a-70a.

essential fact revealed therein—that a curing method previously used in the United States was capable of, and indeed was the probable cause for, the production of tobacco with low to undetectable levels of TSNA—should not have been kept from the PTO.

Id. at 71a. The district court characterized as “critical” the prior art information showing low TSNA levels achieved with established curing methods, *id.* at 71a-72a, and quoted in support an October 25, 2000 letter written by Star’s lead trial lawyer: “The fact that the traditional heat exchange curing process might have produced low-TSNA leaf some of the time, raises the issue of whether the product claimed [by the applications for the Patents-in-Suit] are novel, as required by 35 U.S.C. § 102.” *Id.* at 72a.

Having found the withheld information material, the district court focused on the extended period of non-disclosure—nearly four years—in concluding “that RJR has established the intent to deceive by Williams and others by clear and convincing evidence.” Pet. App. 72a.

They engaged in a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco. The scheme started with the false statement [in the provisional application that led to the ‘649 patent] that “[i]t has been determined that this process as applied to tobacco grown in the United State[s] yields tobacco products with high levels of TSNA,” and proceeded through the entire course of prosecution in the PTO.

Id.

The district court also noted that the prior art information continued to be withheld after the '649 patent had issued and the '401 patent was still pending, even though a discussion among Star's lawyers suggested disclosure. Pet. App. 74a-75a; *see also id.* at 68a. The district court rejected the alleged non-deceptive explanation—a desire to avoid cost and delay—offered by patent counsel Rivard for failing to disclose the Burton letter and Curran data when he finally became aware of them in June 2002, after the notice of allowance of the '401 patent had issued. *Id.* at 75a. It found such reasoning to be inconsistent with “a purported practice of erring on the side of disclosure,” *id.* at 73a, and with Rivard's statement that he would have disclosed the information had he known about it earlier. *Id.* at 74a; App. A258. *See* App. A239-240.

Nowhere in the section of the decision that the court labeled its “Determination” did the district court even mention the shift of law firms that occurred in the middle of the patent prosecution.⁷ Instead, it relied on the conduct over several years, including the fact that the disputed prior art was highly material, and the persistent unexplained failure to disclose throughout the extended patent process. Pet. App. 71a-72a. After weighing the equities based on “a strong showing of materiality and intent,” the court held the patents unenforceable. *Id.* at 76a.

⁷ The court discussed the change of law firms earlier, during its discussion of all the background facts. Pet. App. 54a.

D. The Federal Circuit's Inequitable Conduct Decision

The Federal Circuit reversed the trial court's inequitable conduct ruling as to both patents. With regard to the '649 patent, the panel reversed as clearly erroneous the finding of intent to deceive, but left undisturbed the finding that the undisclosed information was material. Pet. App. 12a, 18a n.8.

With regard to the '401 patent, the panel left standing the finding of intent to deceive, but reversed on materiality because immediately prior to the issuance of that patent in 2002, Star submitted Reynolds' interrogatory responses that the Federal Circuit said rendered the undisclosed information cumulative. Pet. App. 22a-25a.

The panel noted the need to "be vigilant in not permitting the defense [of inequitable conduct] to be applied too lightly." Pet. App. 14a. It described intent to deceive as "a separate and essential component of inequitable conduct," *id.*, and stated that withholding material information "cannot, by itself, satisfy the deceptive intent element," *id.* at 15a. In assessing the evidence of intent, the Federal Circuit never acknowledged the trial court's actual rationale that persistent failure to disclose over an extended period is itself powerful evidence of such intent, *id.* at 72a-75a, and instead asserted:

Here, the district court's finding of deceptive intent as to both patents-in-suit was based primarily on its acceptance of RJR's theory that Williams and Star conspired to deliberately prevent Delmendo and his colleagues at the Sughrue firm from disclosing the Burton letter to the PTO by replacing them with the Banner

firm and purposely keeping the Banner firm ignorant of the Burton letter. We hold that this "quarantine" theory was not supported by clear and convincing evidence.

Pet. App. 17a; *id.* n.7 (acknowledging false statements in the provisional application).

The panel found that Star had offered reasons (relating to personnel changes) for the change in firms. Pet. App. 18a. Noting that the trial court found this testimony not credible, and that "this credibility determination was a major basis for its finding of deceptive intent," the panel responded that Reynolds had the burden of proof and the "patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence." *Id.* at 18a-19a. The panel found that Reynolds had failed to present evidence sufficient to show a deceitful purpose behind the firm change, *id.* at 19a, and on this basis, held the finding of deceptive intent as to the '649 patent clearly erroneous.

With respect to the '401 patent, the panel noted that "the district court also relied on additional evidence to find inequitable conduct"—primarily the decision to continue withholding the prior art even though communications among Star's lawyers suggested a contrary course. Pet. App. 22a, 66a-68a. Noting that the "district court's finding of deceptive intent . . . may [still] be flawed," the panel left that issue unresolved and instead reversed on materiality. *Id.* at 22a.

The panel explained that, following issuance of the '649 patent, in the course of the patent infringement litigation, Reynolds had given interrogatory re-

sponses stating that “Reynolds recognized in or about 1994 that tobacco . . . cured in the indirect fired barns *had significantly reduced levels of TSNA*s as compared to the commercial, direct-fired, bulk curing barns” Pet. App. 24a (emphasis in original). These were disclosed to the PTO during 2002, after the ‘401 patent had already been allowed, and shortly before it issued in July 2002, *id.* at 8a-9a, with an accompanying notation that Star disagreed with the assertion. App. A10419. The Federal Circuit concluded that these responses contained the essential information that existing curing methods had achieved low TSNA levels, thus rendering the withheld information cumulative with regard to the ‘401 prosecution by the time “the Banner lawyers were made aware of [it] in June 2002.” Pet. App. 24a.

Reynolds filed a petition for rehearing and rehearing *en banc*, which was denied on October 22, 2008.

REASONS FOR GRANTING THE WRIT

The Federal Circuit’s contortions to overturn the trial court’s considered fact-finding based on a full-trial record, articulated credibility concerns, and reasonable inferences drawn from applicant’s misleading statements and prolonged non-disclosure of material information require the attention of this Court.

The functioning of the patent system within the constitutional limitation that patent monopolies must “[p]romote the progress of . . . useful [a]rts,” U.S. Const. art. I, § 8, cl. 8, means that patent applicants must conduct themselves with the “highest degree of candor and good faith,” *Kingsland v. Dorsey*, 338 U.S. at 319. “Public interest demands that all

facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies." *Precision Instrument*, 324 U.S. at 818.

The inequitable conduct doctrine, which allows patents to be held unenforceable when there is an intentional breach of the duty of candor, is an essential bulwark in confining patent monopolies to their constitutional limits. Apparently influenced by "the severity of the penalty" of unenforceability, Pet. App. 14a, the Federal Circuit decision here departs from common sense and the mainstream of its own decisions to announce an approach that greatly undermines the duty of candor by making proof of intent to deceive a difficult scholastic exercise. In setting aside the trial court's well-grounded findings without discussing its actual reasoning, the decision is also a gross affront to this Court's principles governing appellate review of trial court fact-finding.

**I. THE DECISION BELOW MARKEDLY
NARROWS THE INEQUITABLE CONDUCT
DEFENSE IN A MANNER AT ODDS WITH
PREVIOUS FEDERAL CIRCUIT DECISIONS
AND WITH DECISIONS OF OTHER CIRCUITS**

The decision below reversed the trial court's finding of deceptive intent as to the '649 patent, even though that finding rested on express misrepresentations to the PTO and a carefully-analyzed pattern of conduct revealing "a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco." Pet. App. 72a. The Federal Circuit did not dispute the materiality of the

withheld information, and also did not even discuss the trial court's reasoning that prolonged non-disclosure of such information in the face of a clear duty to disclose supports an inference of intent to mislead. *See* Pet. App. 17a.

Instead, the Federal Circuit focused on events surrounding a change of law firms, wrongly asserting that these events were the primary basis for the finding of deceptive intent. Pet. App. 17a-18a. It followed this course after commenting at some length about the "separate" nature of the elements of materiality and intent to deceive, *id.* at 14a, and the "need to strictly enforce the . . . elevated standard of proof . . . because the penalty . . . is so severe." *Id.* at 13a.

In reversing on this record, the decision below is at odds with many Federal Circuit decisions and those of regional courts of appeals reviewing inequitable conduct findings, which take a more conventional approach to appellate review. As such, it evidences a sharp divide in thinking among the judges of the Federal Circuit, and threatens the special need recognized by Congress for "nationwide uniformity in patent law," *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (quoting H.R. Rep. No. 97-312, at 20 (1981)) (internal quotation marks omitted). If uncorrected, it is likely to result in unpredictable and irreconcilable decisions. *See, e.g., Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (noting that divisions within the Federal Circuit warrant review by this Court); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993) (noting that uniformity of patent law "is a matter of special importance to the

entire Nation”); *see also, e.g., Dickinson v. Petroleum Conversion Corp.*, 338 U.S. 507, 508 (1950) (finding that an “intracircuit conflict” can support certiorari).

The decision below directs that the inequitable conduct defense not be “applied too lightly,” and that intent to deceive is an “essential component of inequitable conduct” “separate” from materiality. Pet. App. 14a. Perhaps on that account, the panel failed even to discuss the actual rationale of the trial court’s inference of intent, based in substantial part on the prolonged failure to disclose known, concededly material prior art.

In that regard, the decision here departs sharply from prior decisions of the Federal Circuit, which view the materiality of withheld information as relevant in assessing intent. Indeed, some cases have held that the requirement of actual intent may be replaced by a lesser requirement that the applicant merely should have known of the materiality of a withheld reference if the materiality of the reference is sufficiently significant.

This line of cases is exemplified by *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006), which held that, where an applicant offers no credible explanation for withholding known highly material information, no proof of actual intent is required and it is enough that the applicant “*should have known* of the materiality of the information.” *Id.* at 1191 (emphasis added).

In evaluating whether this “should have known” intent standard is applicable, *Ferring* considered the full range of circumstantial evidence, including evidence related to materiality. *See id.* Panels of the

Federal Circuit have reiterated this “knew or should have known” standard in a number of other cases. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-15, 1318 (Fed. Cir. 2008); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1367 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007).

Other Federal Circuit decisions conflict with the decision below by permitting the consideration of materiality as evidence of intent, even where actual intent continues to be required. Thus, in *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000), the panel held that “[t]he more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find that inequitable conduct has occurred.” *Id.* at 1378. Panels in other cases have held similarly. *See, e.g., Honeywell Int’l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007) (“The more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find inequitable conduct.”); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (holding that “a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead” (internal quotation omitted)); *see also Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003). For instance, the panel in *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007), *cert. denied*, 128 S.Ct. 375 (2007), and 128 S.Ct. 391 (2007), con-

cluded that, while “the evidence reveal[ed] less than an egregiously willful intent to deceive” the PTO, an inequitable conduct determination was proper “in light of the high materiality of the nondisclosure.” *Id.* at 1346 n.4.

The Federal Circuit’s ordinary consideration of materiality evidence in evaluating intent is illustrated by *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), which affirmed a finding of inequitable conduct based significantly on the principle that intent may be inferred from “[t]he high materiality of the withheld prior art coupled with the lack of a credible explanation for the nondisclosure.” *Id.* at 916 (internal quotation omitted). Similarly, *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334 (Fed. Cir. 2008), held that an inventor’s failure to disclose information about certain data constituted inequitable conduct, concluding that the denials of one involved in the process “did not outweigh the cumulative evidence evincing an intent to deceive.” *Id.* at 1348.

The decision below was foreshadowed by dissenting opinions in several previous cases. For example, in *Aventis*, Judge Rader in dissent characterized inequitable conduct as an “atomic bomb” remedy, and argued that the case furthered a trend in “emphasiz[ing] materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct,” and of “[m]erging intent and materiality.” *Id.* at 1349-50. Judge Newman similarly dissented in *Ferring*, noting the inconsistency in the Federal Circuit’s inequitable conduct cases, and claiming that the panel majority had “replac[ed] the

need for evidence with a 'should have known' standard" in alleged contravention of Federal Circuit precedent. 437 F.3d at 1196. Judge Newman also dissented in *McKesson*, contending that the panel majority had improperly weakened the standard for proving intent. *See* 487 F.3d at 926.

The decision below, in its sharp departure from prior Circuit precedent, thus brings to a head a simmering dispute among the judges of the Federal Circuit regarding the propriety of relying on the materiality of misstatements or omissions in assessing deceptive intent. By offering guidance on the "separate" character of the materiality and intent inquiries, and then wholly ignoring the trial court's reliance on the materiality of the undisclosed prior art, *see* Pet. App. 17a—which the Federal Circuit did not dispute—the court here compounded a confusion in Federal Circuit inequitable conduct law that was already well recognized.⁸

In addition to being out of step with other Federal Circuit decisions, the decision below is in even sharper conflict with decisions of the regional courts

⁸ *See, e.g.,* Scott D. Anderson, *Inequitable Conduct: Persistent Problems and Recommended Resolutions*, 82 Marq. L. Rev. 845, 848-49 (1999) (noting the Federal Circuit's "narrow and inconsistent interpretations" of inequitable conduct standards, "which confuses patent applicants, complicates patent prosecution, and misleads district court judges"); Michael A. Weidinger, Note, *Inequitable Pleading: Defendants' Particular Burden in Patent Infringement Suits*, 62 Geo. Wash. L. Rev. 1178, 1188 (1994) (noting that the Federal Circuit standards "have changed rapidly," "causing confusion in the patent bar," and producing "confused standards").

of appeals.⁹ Indeed, there is a stark and longstanding circuit split over whether the "intent" prong of the inequitable conduct test requires, as a general matter, actual intent or merely recklessness or gross negligence.

In the decision below, the Federal Circuit followed its own precedent in expressly requiring a finding of specific intent to deceive. Pet. App. 13a; *see also Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873-74 (Fed. Cir. 1988) (en banc) (rejecting gross negligence standard). The First Circuit, however, has held, to the contrary, that "reckless, or grossly negligent conduct" can suffice to satisfy the mental state prong of the inequitable conduct analysis. *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 709 (1st Cir. 1981); *see also Int'l Tel. & Tel. Corp. v. Raychem Corp.*, 538 F.2d 453, 461 (1st Cir. 1976) (same). The Tenth Circuit has similarly held that intent is not required, and that recklessness or gross negligence may be enough. *See True*

⁹ The Federal Circuit's nationwide patent jurisdiction does not render this circuit split inert or irrelevant, because the regional circuits continue to decide issues of patent law in some cases, such as where patent issues are raised in counterclaims under *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826, 834 (2002). *See, e.g., Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807 (8th Cir. 2005) (regional circuit deciding inequitable conduct issue). Justice Stevens's separate opinion in *Holmes Group* specifically noted that because "other circuits will have some role to play in the development of" patent law, "[a]n occasional conflict in decisions [could] be useful in identifying questions that merit this Court's attention." 535 U.S. at 839 (Stevens, J., concurring in part and concurring in the judgment).

Temper Corp. v. CF&I Steel Corp., 601 F.2d 495, 501, 504-05 (10th Cir. 1979). *See also A.H. Emery Co. v. Marcan Prods. Corp.*, 389 F.2d 11, 18 (2d Cir. 1968). The D.C. Circuit has noted the division over whether something less than actual intent may suffice, but reserved the question. *See Turzillo v. P&Z Mergentime*, 532 F.2d 1393, 1400 (D.C. Cir. 1976).

These cases present a sharp and irreconcilable split over the requisite mental state under the inequitable conduct doctrine. They also serve more generally to highlight how greatly the Federal Circuit here has departed from traditional approaches to proving intent, and to show the extent of the confusion that the decision here is likely to sow.

II. IN REVERSING THE DISTRICT COURT'S FINDINGS OF INEQUITABLE CONDUCT, THE FEDERAL CIRCUIT VIOLATED THIS COURT'S PRECEDENTS REGARDING THE USE OF CIRCUMSTANTIAL EVIDENCE AND THE PROPER ROLE OF APPELLATE COURTS

A. The Decision Below Offends Basic Principles Governing Trial Court Factfinding Based on Circumstantial Evidence

The law "makes no distinction between the weight or value to be given to either direct or circumstantial evidence," *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 100 (2003) (quotation omitted), and "[t]he trier of fact should consider all the evidence, giving it whatever weight and credence it deserves." *U.S. Postal Serv. Bd. Of Governors v. Aikens*, 460 U.S. 711, 714 n.3 (1983). Indeed, "[t]he intent . . . that a person possesses at any given time may not ordinarily be proved directly," and thus usually must be shown by circumstantial evidence. Kevin F. O'Malley, *et al.*,

Federal Jury Practice and Instructions § 17:07 (6th ed. 2008) (treatise cited at 539 U.S. at 100).

Many of this Court's cases uphold proof of specific intent—including as an element of a crime where proof beyond a reasonable doubt is required—based on circumstantial evidence less compelling than that rejected *sub silentio* by the Federal Circuit. Indeed, this Court has approved inferences based on circumstantial evidence much like the one relied upon by the trial court—that improper conduct is more likely done with culpable intent where it is done repeatedly or over an extended period of time.

In *Jackson v. Virginia*, 443 U.S. 307, 325 (1979), for example, the Court found sufficient the proof of premeditated intent to kill based on circumstantial evidence including the facts that the “petitioner shot the victim not once but twice.”

In *Holland v. United States*, 348 U.S. 121, 139-140 (1954), in affirming a conviction for tax evasion, the Court concluded that the jury could have found specific intent based on “a consistent pattern of under-reporting large amounts of income, and . . . failure . . . to include all of their income in their books and records.” *Id.* at 139.

Likewise, in *Huddleston v. United States*, 485 U.S. 681 (1988), the Court affirmed a district court's allowance of evidence that a defendant had twice before dealt in goods under suspicious circumstances to prove that the defendant knew certain goods were stolen. The Court explained that “[e]xtrinsic acts evidence may be critical to the establishment of the truth as to a disputed issue, especially when that issue involves the actor's state of mind and the only

means of ascertaining that mental state is by drawing inferences from conduct.” *Id.* at 685.

Similarly, this Court has made clear that a prosecutor’s conduct in making peremptory challenges can support discriminatory intent under *Batson v. Kentucky*, 476 U.S. 79 (1986). In *Miller-El v. Cockrell*, 537 U.S. 322 (2003), the Court found that the disproportionate use of peremptory challenges and differential questioning with regard to African-American jurors was probative of discriminatory intent. *See id.* at 342, 344.

Certainly, the inference of intent to deceive drawn by the district court in this case, based on a patent applicant who claims an invention to produce low TSNA tobacco and fails over several years to disclose known evidence of such tobacco being produced by existing methods, is no less reasonable than the inferences drawn in these cases. Yet the Federal Circuit here apparently deemed that inference unworthy even of discussion. *See* Pet. App. 17a.

B. The Decision Below Also Violates This Court’s Clear Directives Concerning the Role of Appellate Courts in Reviewing Trial Court Factfinding

The Federal Circuit also ignored this Court’s admonitions about the proper role of appellate courts in reviewing trial court factfinding. While the court claimed to review for clear error, Pet. App. 12a, it did not reference the relevant question such review raises—“whether, after viewing the evidence in the light most favorable to the [facts found below], *any* rational trier of fact” could have found intent. *Jackson*, 443 U.S. at 319.

Determining the weight of the evidence "is the special province of the trier of fact," *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 856 (1982), and a "reviewing court oversteps the bounds of its duty under Rule 52(a) if it undertakes to duplicate the role of the lower court." *Anderson v. City of Bessemer*, 470 U.S. 564, 573 (1985). "There is no exception which permits [a party] . . . to come to this Court for what virtually amounts to a trial *de novo* on the record of such findings as intent, motive and design." *United States v. Yellow Cab Co.*, 338 U.S. 338, 341-42 (1949). Thus, "[w]here there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson*, 470 U.S. at 574.

This point has a heightened importance where, as here, trial court factfinding is premised upon determinations of witness credibility. *See* Pet. App. 54a, 59a-60a, 68a-70a, 74a. "When findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings" *Anderson*, 470 U.S. at 575. Yet the Federal Circuit gave no deference to the several credibility judgments by the trial judge who heard the witnesses, including inventor Williams whose intent to deceive is most centrally at issue. Pet. App. 54a-55a, 59a, 69a-70a.

Ultimately, the Federal Circuit did not even acknowledge the trial court's explicit rationale that intent to deceive was shown in part by the prolonged and repeated failure to disclose known, highly material information, in the face of a legal duty to do so. Pet. App. 71a-72a. Far from deferring to the trial court findings if reasonable, the Federal Circuit here

simply ignored them, and reversed based on a lengthy discussion of a minor piece of the overall evidentiary record.¹⁰

C. The Federal Circuit's Approach to Appellate Review and Trial Court Assessment of Circumstantial Evidence Cannot Be Defended on the Basis that a Different Approach is Appropriate in Patent Cases

The decision below warns that courts must "be vigilant in not permitting the defense to be applied too lightly." Pet. App. 14a. In this statement the court mirrors sentiments that have appeared from time-to-time in Federal Circuit cases.¹¹ Whatever the relevance of those sentiments, they cannot mean that well-established principles governing appellate review of trial court factfinding are somehow less applicable where inequitable conduct is in issue.

This Court has recently noted that "familiar principles apply with equal force to disputes arising un-

¹⁰ Moreover, the Federal Circuit held that a finding of intent "must . . . be the single most reasonable inference able to be drawn from the evidence. . . ." Pet. App. 15a-16a. To the extent this statement is intended to govern appellate review of trial court findings, it is obviously unsound in that it substitutes the judgment of appellate court for that of the initial factfinder.

¹¹ See, e.g., *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008) (referring to inequitable conduct as a "plague"); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1195 (Fed. Cir. 2006) (opining that the inequitable conduct doctrine was "grossly misused," leading to "disproportionally pernicious" consequences) (Newman, J., dissenting); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (referring to inequitable conduct claims as "an absolute plague").

der the Patent Act." *Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). It has also recognized the risk that a specialized patent court "may develop an institutional bias." *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring in part and concurring in the judgment). In *Ebay*, this Court rejected a special departure from the "well-established principles of equity" governing the issuance of injunctions in patent cases. 547 U.S. at 391. In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1742-43 (2007), the Court similarly rejected a novel approach to obviousness, referring to a Federal Circuit approach there as "rigid" and denying "factfinders recourse to common sense."

The Federal Circuit's reversal of the trial court's exercise of common sense in this case is no more acceptable. Indeed, it is at odds with decisions of this Court addressing factfinding and appellate review in patent cases. In *Precision Instrument Manufacturing Co.*, this Court rejected an appellate reversal of a district court finding of inequitable conduct following a trial "on the sole issue of . . . alleged inequitable conduct." 324 U.S. at 808. In reinstating the district court's inequitable conduct determination, this Court surveyed the evidence relied upon by the district court in finding inequitable conduct and found it sufficient. *See id.* at 818. The Court held that the patentee should have disclosed misstatements to the PTO, despite the fact that "it did not have positive and conclusive knowledge" of them at the time because the misstatements had occurred before it had been assigned the patent application. *Id.* at 816-17. The Court held that a patent applicant's duty of disclosure to the PTO "is not excused by reasonable

doubts as to the sufficiency of the proof of the inequitable conduct." *Id.* at 818.

Similarly, in *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), the court of appeals had reversed a finding of patent misuse and anti-trust violation. This Court reversed the court of appeals, noting that "Zenith's evidence, although by no means conclusive, was sufficient to sustain the inference that Zenith had in fact been injured." *Id.* at 114. The opinion emphasized that "appellate courts must constantly have in mind that their function is not to decide factual issues *de novo*. The authority of an appellate court, when reviewing the findings of a judge as well as those of a jury, is circumscribed by the deference it must give to decisions of the trier of the fact, who is usually in a superior position to appraise and weigh the evidence," *id.* at 123.

This Court's more recent GVR decision in *Dennison Manufacturing Co. v. Panduit Corp.*, 475 U.S. 809 (1986), was premised on the same principles. *Dennison* vacated a Federal Circuit decision on obviousness. As here, the district court decision under review (there, a finding of obviousness) was made "by clear and convincing evidence," *id.* at 810, and the Federal Circuit reversed under a clear error standard of review. This Court vacated the Federal Circuit's decision in light of the petitioner's contention that the Federal Circuit had improperly "substitut[ed] its view of factual issues for that of the District Court." *Id.* Finding this contention "not insubstantial," *id.*, this Court vacated and remanded for further proceedings.

Accordingly, this Court should grant review to make clear that there are no special limitations upon

the trial court's assessment of circumstantial evidence of intent applicable to inequitable conduct or to patent cases, and to reaffirm that the Federal Circuit is no different than other circuits in its appellate role.

III. THE DECISION BELOW CREATES GREAT CONFUSION AND WEAKENS THE DUTY OF CANDOR BY PLACING A VERY HIGH THRESHOLD ON PROOF OF INEQUITABLE CONDUCT

The inequitable conduct defense is raised in more than half of all patent infringement cases. *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Procurement*, Ad Hoc Committee on Rule 56 and Inequitable Conduct American Intellectual Property Law Association, 16 AIPLA Q.J. 74, 75 (1988). The proper standard for its proof, and the way in which trial courts are to assess the evidence, including whether and how the materiality of misstatements or omissions may be probative of intent, is thus a matter of utmost importance in patent litigation.

Moreover, the issue is one of constitutional dimension, as the inequitable conduct doctrine plays an important role in policing the constitutional boundary on the power to issue temporary patent monopolies only for the purpose of encouraging genuine innovations. See U.S. Const. art. I, § 8; *Graham*, 383 U.S. at 5. "[T]he limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that

monopoly.” *Kendall v. Winsor*, 62 U.S. 322, 327-28 (1858).

Wrongly issued patents obstruct the free interchange of ideas and technological developments. *See, e.g., Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Thus, this Court has long emphasized the public importance of precluding enforcement of wrongfully issued patents. *See, e.g., Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) (noting that it is “important to the public that competition should not be repressed by worthless patents”). Consequently, issues relating to the propriety of the issuance of a patent are even more important than questions relating to infringement. *See, e.g., Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945).

Because the PTO is charged with making the decisions regarding patentability in the first instance, and because the task of sorting patentable from unpatentable subject matter is “most difficult”, *Graham*, 383 U.S. at 18, this Court has emphasized the uncompromising duty of candor owed by “[t]hose who have applications pending with the Patent Office.” *Precision Instrument*, 324 U.S. at 818. *See also, e.g., Kingsland*, 338 U.S. at 319.

The need for full candor in dealings with the PTO is all the more crucial in light of the “record workload crisis” that Office faces. Jon W. Dudas, *The Patent System: Today and Tomorrow*, at 4, at www.uspto.gov/web/offices/com/speeches/2005apr21.pdf (Apr. 21, 2005) (visited Jan. 4, 2009). Applications more than doubled between 1992 and 2005, with the greatest increases in the most complex subject areas, and there is recognized need for patent

applicants to share the burden of improving the system's functioning. *Id.* at 3, 8.

The critical nature of the issue here for all of those reasons is compounded further by the greatly expanded volume of patent litigation in recent years, the fact that it is a "very costly process," *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 334 (1971), and the tremendous importance of patents to American commerce and industry. For all of these reasons, this case merits the Court's attention.

IV. THE FEDERAL CIRCUIT'S DECISION REVERSING THE TRIAL COURT'S FINDINGS OF INEQUITABLE CONDUCT ON BOTH PATENTS IS WRONG ON THE MERITS

The court below should have decided whether the trial court could reasonably have found clear and convincing evidence that Williams and those assisting him made material misstatements or omissions with intent to mislead the PTO. After evaluation of the evidence received at a lengthy trial, this was not a difficult question for the trial court, and it should not have been a close one for the Federal Circuit either.

The district court found that Williams failed over a period of years to disclose known evidence that curing methods used in the United States could produce low or undetectable TSNA levels. Pet. App. 71a-72a; App. A290 (Williams admits such knowledge by September 15, 1998). The court found this known prior art to be highly material. *Id.* It also found flatly false the provisional application's statement—that came from Williams, App. A217, A289—that the longstanding radiant heating method had been de-

terminated to produce high TSNA tobacco. The district court's several credibility findings, Pet. App. 54a, 59a-60a, 68a-70a, 74a, and other factors, led it to discount various testimony asserting non-materiality or explaining why the information had not been produced. *Id.* at 66a-70a, 74a-75a. On all these grounds, the district court concluded that "Williams and others deliberately misled the PTO in a material manner by keeping from [it] the critical fact known to Williams and others that the claimed beneficial result—tobacco with low to undetectable TSNA levels—*had been achieved in the United States* prior to the application that led to the Patents-in-Suit." *Id.* at 43a.

The Federal Circuit did not disturb the finding that the withheld information was material with regard to the '649 patent. It further acknowledged that the statement in the provisional application was "inaccurate." Pet. App. 17a-18a nn.7, 8. Nor did the Federal Circuit ever make reference, *see* Pet. App. 17a, to the trial court's essential reasoning that the persistent non-disclosure of known, highly material prior art over a period of several years, in the face of numerous occasions triggering renewed duties to produce it, is probative of deceptive intent. Instead, the Federal Circuit focused on a straw man, the mid-stream change of law firms, stating falsely that the finding of deceptive intent was based primarily upon that series of events. In this respect, the Federal Circuit seems to have been acting on its assertion that in the world of inequitable conduct, materiality and intent must be proven separately, thus prohibiting the trial court's reliance on materiality.

Had the Federal Circuit considered the reasoning of the trial court and rejected it as beyond the limits of rationality, it would certainly merit reversal as contrary to decisions of this Court affirming inferences of intent on much weaker evidence. The Federal Circuit's failure even to discuss the actual reasoning of the trial court, and reversal for the reasons it gave, is an affront to the judicial process.

The Federal Circuit's reversal of the unenforceability ruling as to the '401 patent is also obviously incorrect. The court conceded that even more evidence of deceptive intent existed as to that patent. Pet. App. 22a. The panel nonetheless reversed on the ground that the prior art at issue, whose previous materiality the court had not disputed, became cumulative in early 2002, when, after the '401 patent had already been allowed, Star submitted to the PTO a Reynolds litigation discovery response asserting that, as of 1994, indirect fired barns had produced "significantly reduced levels of TSNA's." *Id.* at 24a.

The notion that such a litigation response by an obviously interested party, submitted at the eleventh hour, would render cumulative the well-known but long-concealed, objective evidence that low TSNA levels had long been achieved using traditional curing methods, is at best highly implausible.¹² And Star submitted Reynolds' interrogatory responses to the PTO only with the express disclaimer that "Ap-

¹² In addition, the uncontradicted expert testimony was that the Burton letter was not cumulative of the RJR discovery responses for anything else in the record in the prosecution. App. A319, A325-326.

plicant respectfully disagrees with R.J. Reynolds' characterization of the documents." App. A10419.¹³

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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January 16, 2009

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¹³ The facts that the two patents have an identical specification and nearly identical claims—with the '401 patent being somewhat narrower—also strongly suggest that the '401 is unenforceable if the '649 is, under the doctrine of "infectious unenforceability." See *Consol. Aluminum Corp. v. Foseco Int'l. Ltd.*, 910 F.2d 804 (Fed. Cir. 1990); *MOSAID Techs. Inc., v. Samsung Elecs. Co.*, 362 F. Supp. 2d 526, 553-54 (D.N.J. 2005). At a minimum, a finding of inequitable conduct as to the '649 patent would require a remand to assess the continuing enforceability of the '401 patent.

APPENDIX

**STAR SCIENTIFIC, INC.,
Plaintiff-Appellant,**

v.

**R.J. REYNOLDS TOBACCO COMPANY
(a North Carolina Corporation)
and R.J. Reynolds Tobacco Company
(a New Jersey Corporation), Defendants-Appellees.**

No. 2007-1448.

**United States Court of Appeals,
Federal Circuit.**

Aug. 25, 2008.

**Rehearing and Rehearing En Banc
Denied Oct. 22, 2008.**

Carter G. Phillips, Sidley Austin LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Eric A. Shumsky and Peter S. Choi. Of counsel on the brief were Richard McMillan, Jr., Clifton S. Elgarten, Mark M. Supko, and Michael I. Coe, Crowell & Moring LLP, of Washington, DC.

Richard A. Kaplan, Brinks Hofer Gilson & Lion, of Chicago, Illinois, argued for defendants-appellees. With him on the brief were Jerold A. Jacover, Ralph J. Gabric, K. Shannon Mrksich, Cynthia A. Homan, and Julie L. Leichtman.

Before MICHEL, Chief Judge, SCHALL and DYK, Circuit Judges.

MICHEL, Chief Judge.

Plaintiff-Appellant Star Scientific, Inc. ("Star") appeals from a final judgment in favor of Defendants-Appellees R.J. Reynolds Tobacco Company (N.C.) and R.J. Reynolds Tobacco

Company (N.J.) (collectively, "RJR"). The district court entered memoranda and orders: (1) holding, after a bench trial, that Star's U.S. Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent") are unenforceable due to inequitable conduct; and (2) granting summary judgment of invalidity of all asserted claims of the '649 and '401 patents due to indefiniteness. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-1504, 2007 WL 1890709, slip op. at 46 (D. Md. June 26, 2007) ("*Inequitable Conduct Order*"); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-1504, slip op. at 12-14 (D. Md. June 22, 2007) ("*Indefiniteness Order*").

Because the district court's judgment as to inequitable conduct was based on factual findings that we deem clearly erroneous, we reverse the judgment of unenforceability of the '649 and '401 patents. We also reverse the grant of summary judgment as to indefiniteness because we conclude that the claim term at issue, "anaerobic condition," is not indefinite, and we remand for further proceedings on infringement and validity.

I. BACKGROUND

A. Tobacco Curing Technology

Fresh tobacco ("green tobacco") must be dried in a process called "curing" before it is suitable for consumption as cigarettes or other such products. Curing is done in curing "barns," and commercial tobacco companies like RJR cure their tobacco in bulk-curing barns in which substantial quantities of harvested tobacco are cured together in large stacks. Smaller operations may use the older and long-used

technology of "stick barns" in which much smaller quantities of tobacco are cured.

Four major mechanisms of curing have been used in the United States:

- (1) air curing, where the tobacco is air-dried without the application of heat;
- (2) radiant heat indirect-fired curing ("radiant heat curing"), where fuel (typically oil) is burned and the hot exhaust gases are passed through pipes running through the barn such that the hot pipes radiate heat into the barn to dry the tobacco, but the exhaust gases are then expelled outside the barn;
- (3) direct-fired curing, where fuel (typically propane) is burned and the hot exhaust gases themselves are blown directly into the barn to dry the tobacco; and
- (4) forced air indirect-fired curing, where fuel is burned to heat clean air that is then blown into the barn to dry the tobacco, while the exhaust gases from the fuel burning are expelled outside the barn.

In the 1960s, the primary method used by American tobacco companies was radiant heat curing. By the 1970s, most companies switched to direct-fired curing, which was the predominant method used until at least the late 1990s.

Cured tobacco contains a number of hazardous chemicals, including carcinogens known as tobacco specific nitrosamines ("TSNAs"), which are not present in green tobacco. In the 1990s, researchers began to explore TSNA formation in tobacco and discovered links between TSNAs and direct-fired

curing. As a result, some researchers began to investigate how curing methods could be altered to minimize TSNA formation.

B. The '649 Patent

In August 1998, Jonnie Williams of Star engaged attorney Romulo Delmendo of Sughrue, Mion, Zinn, Macpeak & Seas ("the Sughrue firm") to prosecute a patent application on a tobacco curing process aimed at lowering TSNA levels. Williams, the inventor, believed that TSNA's were formed due to the presence of microbes on the tobacco leaves. According to this theory, ambient oxygen in the vicinity of the drying leaves is reduced during cure by the production of carbon dioxide as the green tobacco leaves degrade and by the oxygen-poor combustion gases blown in during direct-fired curing. The microbes thus must operate anaerobically and obtain oxygen through reduction-oxidation reactions involving nitrates also produced from leaf degradation. Those reactions produce nitrites, which in turn form TSNA's through further chemical reactions. Williams' method sought to prevent TSNA formation by lessening the drop in oxygen levels through control of airflow, humidity and temperature inside the curing barn, thereby reducing the microbes' need to resort to anaerobic processes.

As part of the preparation of Williams' patent application, Delmendo was sent a letter on August 28, 1998, by scientist and Star consultant Dr. Harold Burton ("the Burton letter"). Burton wrote to relate his recent observation that Chinese tobacco products contain very low TSNA levels. The Burton letter further stated:

Since China is a developing country, they are still use [sic] the old curing technology that was abandoned in the U.S. during the sixties. It seemed to me that the probable cause for the absence of TSNA was their use of the old [radiant heat] flue-curing techniques.

J.A. at A6237. Delmendo testified that although he was initially concerned about the information, he then spoke with Burton, analyzed the letter, and ultimately concluded that neither it nor its content was material to the contemplated patent application.

Delmendo filed with the United States Patent and Trademark Office ("PTO") a provisional patent application, Application Serial No. 60/100,372 ("the Provisional"), on behalf of Williams on September 15, 1998. The application disclosed that some nations, including China, still utilize radiant heat curing. J.A. at A5808-09. The disclosure also stated: "It has been determined that [the radiant heat] process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA." *Id.* at A5809. Williams testified that this statement was based on inferences he drew from information he received from Brown & Williamson, another tobacco company, indicating that Brazilian tobacco cured using radiant heat techniques resulted in TSNA levels of 2-3 ppm.

Shortly after the Provisional was filed, Williams received samples from two Virginia farms that still used radiant heat curing and forwarded them to Burton for measurements of TSNA content. The first, from the Jennings farm, contained 1.0-1.5 ppm TSNA's ("the Jennings data"). The second, from the Curran farm, contained 0.39 ppm ("the Curran data"). Unlike the Jennings data, however, the

Curran data was derived from a partially-cured sample; the sample was partially-cured using radiant heat curing, but Williams' associate completed the cure using a microwave prior to Burton's tests.¹ Williams informed Delmendo of the Jennings data over the phone but never showed him the actual data in document form. He did not inform Delmendo of the Curran data. Delmendo testified that he and Williams considered the Jennings data to be relevant but not a significant concern because Williams' method produced a significantly greater reduction in TSNA's.²

On September 15, 1999, exactly one year after filing the Provisional, Delmendo filed Application Serial No. 09/397,018 ("the '018 application") on behalf of Williams. The '018 application's draft specification adopted most of the Provisional's disclosure but deleted the statement that radiant heat curing of U.S.-grown tobacco produced "high levels of TSNA." Instead, it stated:

In flue curing processes that utilize a heat exchanger capable of providing relatively low airflow through the curing barn, I have discovered that it is *possible to somewhat reduce the TSNA levels by not venting combustive exhaust gases*

¹ It is undisputed that microwave curing produces vastly lower TSNA levels than any indirect-fired or direct-fired curing process.

² According to Delmendo, he understood that direct-fired curing produced TSNA levels exceeding 3.0 ppm, thus the 1.0-1.5 ppm produced by the indirect-fired process on the Jennings farm was "somewhat reduced." J.A. at A219. By contrast, Williams informed Delmendo that his process reduced TSNA levels much further to the 0.1-0.2 ppm range.

into the curing apparatus or barn. The preferred aspects of the present invention are premised on the discovery that other parameters, as identified above (e.g., airflow), can be adjusted to ensure the prevention or reduction of at least one TSNA regardless of the ambient conditions.

'649 patent col.6 ll.22-30 (emphasis added). Delmendo testified that this new disclosure was based on his discussion of the Jennings data with Williams.

Shortly after the filing of the '018 application, Williams and Star elected to terminate the Sughrue attorneys' involvement in the prosecution and replace them with attorneys from Banner & Witcoff ("the Banner firm"), including Paul Rivard and Dale Hoscheit. Hoscheit testified that he met with Delmendo and others from the Sughrue firm to discuss the transfer of files and the status of pending applications. Paul Perito, a partner of the law firm Paul, Hastings, Janofsky & Walker ("Paul Hastings") who became the chairman of Star, tapped Scott Flicker from Paul Hastings to facilitate the transfer of files from the Sughrue firm to the Banner firm. Upon receiving the files, Rivard searched them for prior art but did not notice the Burton letter.

On February 15, 2000, Rivard filed a Petition to Make Special regarding the '018 application, including an Information Disclosure Statement ("IDS") discussing and distinguishing certain prior art. The IDS did not include the Burton letter. The Petition was ultimately granted, and the application was allowed on September 14, 2000, and ultimately issued on March 20, 2001, as the '649 patent.

C. The '401 Patent and the Present Litigation

On September 25, 2000, on behalf of Williams, Rivard filed Application Serial No. 09/668,144 ("the '144 application"), a continuation of the '018 application. Rivard also filed a Petition to Make Special for the '144 application with an accompanying IDS listing many of the same references as his earlier IDS for the petition regarding the '018 application. This IDS also did not include the Burton letter.

Star filed the present suit on May 23, 2001, alleging that RJR infringed claims 4, 12 and 20 of the '649 patent. As the litigation proceeded, Rivard periodically filed supplemental IDSs to the '144 application to disclose to the PTO some of the additional prior art raised by RJR against the '649 patent during discovery. For example, on June 12, 2001, Rivard disclosed RJR's Application Serial No. 09/735,177, which was published on April 26, 2001. Rivard also disclosed RJR's interrogatory responses regarding invalidity along with the cited references. These disclosures continued after the '144 application was allowed in January 2002. In April 2002, the issue fee for the '144 application was paid.

In June 2002, while waiting for the '144 application to issue as a patent, Rivard became aware of the Burton letter and Curran data when Star's trial counsel, Crowell & Moring ("Crowell"), informed him that RJR had raised those documents in the litigation. Rivard's initial reaction was that they should be disclosed out of an abundance of caution. Several Crowell attorneys exchanged e-mails amongst themselves discussing whether they thought the Burton letter and/or Curran data was required to be disclosed to the PTO given that the

'144 application had yet to be issued; several agreed that it may be best to "err on the side of disclosure." J.A. at A10998-99. Meanwhile, Rivard and Hoscheit at the Banner firm conferred and ultimately decided that the Burton letter and the Curran data were not material and thus did not need to be disclosed to the PTO. They were never disclosed to the PTO. The '144 application thus issued as expected on July 30, 2002, as the '401 patent. Star immediately moved to amend its complaint to add allegations that RJR was infringing claim 41 of the '401 patent as well.

D. Claim Construction, Trial and Summary Judgment

Claim 4 of the '649 patent is representative of all of the asserted claims:

A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising:

drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion; and

wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

The district court construed three terms relevant to this appeal: “substantially prevent the formation of at least one nitrosamine,” “controlled environment,” and “anaerobic condition.”

The court construed “substantially prevent the formation of at least one nitrosamine” to mean “the level of at least one of the nitrosamines falls within the following ranges: less than about 0.05 mg/g for NNN, less than about 0.10 mg/g for NAT plus NAG, and less than about 0.05 mg/g for NNK.”³ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-1504, slip op. at 2 (D.Md. Mar. 31, 2004) (“*Markman Order*”). The court then construed “controlled environment” to mean “controlling one or more of humidity, temperature and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs.” *Id.* Finally, the court construed “anaerobic condition” to mean “an oxygen deficient condition (such as is created by an atmosphere of combustion gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity.”⁴ *Id.* at 1–2. These claim constructions are not disputed in this appeal.

The district court held a bench trial on RJR’s inequitable conduct defense in January and February of 2005. Star and RJR also filed cross

³ These abbreviations (*e.g.*, NNN, NNK) represent different known TSNAs. These units of measurement, micrograms per gram (mg/g), are equivalent to parts per million (ppm).

⁴ Nitrate reductase is the enzyme used by the microbes on the surface of curing tobacco leaves to catalyze some of the chemical reactions that ultimately produce TSNAs.

motions for summary judgment on RJR's indefiniteness defense, and RJR filed another summary judgment motion on its anticipation and best mode defenses.

On January 19, 2007, the district court issued its decisions on the parties' summary judgment motions. The court granted RJR's motion for summary judgment that the asserted claims of both patents are invalid for indefiniteness, holding that the term "anaerobic condition" was indefinite. *Indefiniteness Order*, slip op. at 12–14.⁵ The court also denied RJR's motion for summary judgment that the asserted claims are invalid due to anticipation and violations of the best mode requirement, holding that Star raised genuine issues of material fact as to those defenses.⁶ *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01–cv–1504, slip op. at 12–15 (D.Md. Jan. 19, 2007) ("*Anticipation Order*").

On June 26, 2007, the district court issued a decision on RJR's inequitable conduct defense. The

⁵ The district court replaced its January 19, 2007 opinion regarding indefiniteness with a corrected opinion on June 22, 2007, to rectify a minor clerical error.

⁶ The district court purported to grant partial summary judgment to RJR by holding that neither asserted patent could claim priority to the filing date of the Provisional, a predicate to RJR's invalidity arguments. *Anticipation Order*, slip op. at 16. Star argues that this decision was erroneous and should be reversed. However, this holding is not properly before this court since it did not form the basis of any judgment. Priority date in and of itself is not a claim or defense on which summary judgment can be granted, and the district court denied RJR's motion for summary judgment on anticipation and best mode, which RJR does not cross-appeal.

court held both of Star's asserted patents unenforceable due to inequitable conduct and entered final judgment in favor of RJR. *See Inequitable Conduct Order*, slip op. at 46. Star timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Inequitable Conduct

1.

We review the district court's inequitable conduct determination under a two-tier standard; we review the underlying factual determinations for clear error, but we review the ultimate decision as to inequitable conduct for an abuse of discretion. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364–65 (Fed. Cir. 2007). If the district court's determination of inequitable conduct is based on a clearly erroneous finding of materiality and/or intent, it constitutes an abuse of discretion and must be reversed. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006). With respect to the '649 patent, we hold that the district court clearly erred in finding that RJR had proven that Williams and Star had an intent to deceive the PTO. With respect to the '401 patent, we hold that the district court clearly erred in finding that the information contained in the Burton letter and Curran data was material.

The burden of proving inequitable conduct lies with the accused infringer. *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003). To successfully prove inequitable conduct, the accused infringer must present "evidence that the applicant (1) made an affirmative

misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO].” *Cargill*, 476 F.3d at 1363 (citing *Impax Labs.*, 468 F.3d at 1374). Further, at least a threshold level of each element—*i.e.*, both materiality and intent to deceive—must be proven by clear and convincing evidence. *Id.*; *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006). And even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant’s conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable. *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004). Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. This penalty was originally applied only in cases of “fraud on the Patent Office.” *See Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250–51, 64 S.Ct. 997, 88 L.Ed. 1250 (1944); *see also Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381 (1945) (“The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent [grants] spring from backgrounds free from fraud or other inequitable

conduct and that such [grants] are kept within their legitimate scope.”); *Digital Control*, 437 F.3d at 1315 (discussing the roots of inequitable conduct in common law fraud). Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud, see for example *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069–70 (Fed. Cir. 1998), but the severity of the penalty has not changed, and thus courts must be vigilant in not permitting the defense to be applied too lightly. Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

With regard to the deceptive intent prong, we have emphasized that “materiality does not presume intent, which is a separate and essential component of inequitable conduct.” *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). Moreover, as we explained in *Molins PLC Textron, Inc.*:

[T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to . . . mislead[] or deceiv[e] the PTO. In a case involving nondisclosure of

information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.

48 F.3d 1172, 1181 (Fed. Cir. 1995) (emphases added). Thus, the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006). Rather, to prevail on the defense, the accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO. *Id.*; see also *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (holding even gross negligence insufficient to prove intent to deceive).

We have also held that because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. *Cargill*, 476 F.3d at 1364. But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement. See *Ferring*, 437 F.3d at 1186 (“The predicate facts must be proven by clear and convincing evidence.”). Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court

clearly errs in overlooking one inference in favor of another equally reasonable inference.”).

With respect to the materiality prong, we have held that “information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” *Symantec Corp. v. Computer Assocs. Int’l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008); *see also Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006). It is well-established, however, that information is not material if it is cumulative of other information already disclosed to the PTO. *Honeywell Int’l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007) (“Information cumulative of other information already before the Patent Office is not material.”); 37 C.F.R. § 1.56(b) (“[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application . . .”).

If a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities or how it might balance them. *See Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 398 (Fed. Cir. 1996) (holding that the district court properly refrained from balancing materiality and intent when a threshold showing of intent to deceive was not clearly and convincingly made). Only after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings. “The more material the omission or the

misrepresentation, the lower [the] level of intent [is] required to establish inequitable conduct, and vice versa." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). At this second stage, however, the question is no longer whether materiality and/or intent to deceive were proven with evidence that is sufficiently clear and convincing. While the facts of materiality and intent to deceive must be proven by clear and convincing evidence, the district court must balance the *substance* of those now-proven facts and all the equities of the case to determine whether the severe penalty of unenforceability should be imposed. It is this balancing that is committed to the district court's discretion. *Molins*, 48 F.3d at 1178.

2.

Here, the district court's finding of deceptive intent as to both patents-in-suit was based primarily on its acceptance of RJR's theory that Williams and Star conspired to deliberately prevent Delmendo and his colleagues at the Sughrue firm from disclosing the Burton letter to the PTO by replacing them with the Banner firm and purposely keeping the Banner firm ignorant of the Burton letter. We hold that this "quarantine" theory was not supported by clear and convincing evidence.⁷ As a result, we hold that the

⁷ The district court also inferred intent to deceive from the statement in the Provisional that prior art radiant heat curing produced high levels of TSNA's in American tobacco. There is no dispute that this statement was inaccurate. While we do not hold that inaccurate statements made in provisional applications cannot evidence an intent to deceive, we note that provisional applications are not examined and that the alleged misrepresentation here was corrected prior to examination of the non-provisional applications. As such, we hold that this

district court's finding of deceptive intent with regard to the '649 patent was clearly erroneous.⁸

Star's witnesses testified that the reasons behind the replacement of the Sughrue firm were that a key partner passed away and that Williams observed a Sughrue attorney perform unsatisfactorily in an unrelated prosecution. The district court indicated that it viewed this testimony as not credible and that this credibility determination was a major basis for its finding of deceptive intent. Certainly, credibility determinations are an aspect of fact-finding that appellate courts should rarely reverse. But even if Star's explanations are not to be believed, it remained *RJR's* burden to prove its allegation regarding the reason for the Sughrue firm's dismissal. *RJR* cannot carry its burden simply because Star failed to prove a credible alternative explanation. See *M. Eagles Tool Warehouse*, 439 F.3d at 1341 ("When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent."). The patentee need not offer any good faith explanation unless the accused infringer first carried

statement is not clear and convincing evidence of deceptive intent.

⁸ Thus, we need not address whether the district court's finding of materiality as to the '649 patent was clearly erroneous. Regarding the '401 patent, the district court's finding of deceptive intent was in part based on additional evidence concerning events following the issuance of the '649 patent. As explained further below, we need not decide whether that deceptive intent finding was also clearly erroneous because we find the district court's finding of materiality as to the '401 patent clearly erroneous.

his burden to prove a threshold level of intent to deceive by clear and convincing evidence. *Nordberg*, 32 F.3d at 398. Only when the accused infringer has met this burden is it incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct. *See id.*

In reviewing the affirmative evidence, it becomes clear that RJR's evidence had a major gap—RJR failed to elicit any testimony or submit any other evidence indicating that Star knew what the Burton letter said prior to replacing the Sughrue firm, or that the letter was a reason for changing firms. RJR admitted at oral argument that it failed to even ask Williams or Star's other executives about these critical facts, and RJR failed to identify any testimony or other evidence when specifically asked by us to do so in supplemental briefing. Further, a review of the record shows that Williams actually testified, in response to a different question, that he had never seen the Burton letter prior to his deposition in the present litigation. This statement was never impeached, questioned, or explored by RJR's counsel. RJR identified Perito, Star's chairman, as the officer who made the decision to terminate the Sughrue firm, but Perito was never asked whether he had knowledge of the Burton letter or whether it played any role in his decision to change firms. As noted earlier, the district court may infer facts supporting an intent to deceive from indirect evidence. *Cargill*, 476 F.3d at 1364. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR's lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.

Other facts and inferences relied on by the district court do not plug this hole in RJR's evidence. First, the district court found that Delmendo had concerns about whether the information in the Burton letter should be disclosed to the PTO, the suggested inference being that Star would have been motivated to replace him to ensure he did not disclose the letter to the PTO. Indeed, both Delmendo's testimony and his written notes provide evidence supporting the finding that he had such concerns. However, he was not asked whether he ever expressed those concerns to Williams or anyone else at Star. No Star witness was asked whether Delmendo expressed his concerns to them either. This record cannot support an inference that Star was motivated to replace Delmendo due to his concerns about the Burton letter since there is no evidence, let alone clear and convincing evidence, that Star even knew about the letter or his concerns. Again, RJR failed to carry its burden of proof.

Second, the district court also found that Perito's use of an intermediary, Flicker of Paul Hastings, to facilitate the transfer of files from the Sughrue firm to the Banner firm evidenced an intent to prevent any communication between the firms. The inference drawn, therefore, was that Star was deliberately insulating the Banner lawyers from the Sughrue lawyers to prevent the former from learning of Delmendo's concerns regarding the Burton letter. But RJR's failure to adduce any evidence that Star knew of Delmendo's concerns or the Burton letter's contents renders this inference clearly erroneous as well. Moreover, Hoscheit of the Banner firm specifically testified that he did meet with the Sughrue attorneys, and the district court did not

indicate that it found this testimony or Hoscheit in general to not be credible. In fact, it did not address this testimony at all. Furthermore, the district court rejected RJR's allegation that the Sughrue files, and the Burton letter in particular, were tampered with before being conveyed to the Banner firm. Thus, the Banner firm was clearly given the Burton letter. Yet again, RJR failed to provide clear and convincing evidence to support its allegations.

We also question the district court's reliance on the admitted fact that Star never instructed Rivard or his colleagues at the Banner firm to disclose the Burton letter, nor specifically brought it to their attention prior to June 2002. As already noted, RJR failed to provide evidence that Star knew anything about the Burton letter's contents or that the letter raised any concerns relevant to the prosecution of its patents. Thus, the evidence does not support an inference that Star's failure to bring the Burton letter to the Banner firm's attention was motivated by a deceptive intent to keep it from the examiner. And there is no evidence indicating that Williams, Star or their attorneys at the Banner firm became aware of the Burton letter before June 2002, well after the '649 patent issued in March 20, 2001. Given the heavy reliance by the district court on the Burton letter and RJR's "quarantine" theory, the numerous evidentiary failings relating to this theory gives us a "definite and firm conviction" that the resulting finding of deceptive intent as to the '649 patent was clearly erroneous.⁹ *See Molins*, 48 F.3d at 1178.

⁹ To the extent the district court also relied on the non-disclosure of the Curran data, we note that even the district

3.

Because the district court's finding of deceptive intent as to the '401 patent was also heavily based on RJR's "quarantine" theory, that finding is also weakened by the failings in that theory. But the district court also relied on additional evidence to find inequitable conduct as to the '401 patent. As Star concedes, its attorneys at the Banner firm were made aware of the Burton letter and Curran data in June 2002, at which time the '401 patent had not yet been issued.¹⁰ Although Star had the opportunity to disclose them at that time, it did not disclose either document to the PTO. While the district court's finding of deceptive intent even with regard to this additional evidence may be flawed in some respects, we reverse the holding of inequitable conduct as to the '401 patent because the district court's finding of materiality was clearly erroneous.

The district court found that the Burton letter and Curran data disclosed "the essential fact that the prior art could yield low TSNA tobacco at least some of the time," and that this fact was "manifestly material." *Inequitable Conduct Order*, slip op. at 41-42. However, in the course of the prosecution of the '401 patent, Star disclosed to the PTO other references that made this information contained in the Burton letter and Curran data clearly

court acknowledged that the materiality of the Curran data was questionable given that the Curran tobacco was partially cured using a microwave.

¹⁰ It is clear that the events in June 2002 and the events that followed cannot render the '649 patent unenforceable due to inequitable conduct because the '649 patent had already issued.

cumulative.¹¹ Star points to the disclosure of several references, including RJR's interrogatory responses from this litigation and the language of the '401 patent's specification.

The '401 patent's specification, like the '649 patent's specification, states:

In flue curing processes that utilize a heat exchanger capable of providing relatively low airflow through the curing barn, I have discovered that it is possible to *somewhat reduce* the TSNA levels by not venting combustive exhaust gases into the curing apparatus or barn.

'401 patent, col.6 ll.27-31 (emphasis added). Thus, the specification points out that "somewhat reduce[d]" levels of TSNA were previously attainable. This alone may not render cumulative the Burton letter's disclosure that low to undetectable levels of TSNA were previously unattainable, but another disclosure fills this gap.

In particular, Star disclosed RJR's interrogatory responses produced during the '649 patent infringement litigation. Of particular relevance is interrogatory question number 1:

Describe in detail all research, field tests or other studies that you or others on your behalf have conducted, sponsored, or participated in regarding TSNA formation and/or reduction (including, without limitation, work conducted in Greece,

¹¹ These disclosures were made after the '649 patent was issued, thus our analysis of materiality here applies only to the '401 patent. As already discussed, we reverse the holding of inequitable conduct as to the '649 patent due to the clearly erroneous finding of deceptive intent with regard to that patent.

Turkey or North Carolina), including the results of such research, test or study, and any documents concerning such research, test or study.

J.A. at 6303. RJR's response to that interrogatory provided that: "Reynolds recognized in or about 1994 that tobacco (whether flue-cured or burley) cured in the indirect fired barns *had significantly reduced levels of TSNA*s as compared to the commercial direct-fired, bulk curing barns at Reynolds' Avoca facility." J.A. at 6305 (emphasis added). Also, "[b]y about 1997, Reynolds recognized that it was the absence of combustion exhaust gases in the indirect fired barns that was responsible for the *significantly reduced TSNA levels* obtained in flue-cured tobacco cured in those barns." *Id.* (emphasis added). "Reynolds then confirmed that tobacco cured in existing commercial, indirect-fired, bulk curing barns also contained *significantly reduced levels of TSNA*s as compared to tobacco cured in the commercial, gas-fired, bulk curing barns." J.A. at 6305-06 (emphasis added). The interrogatory response also provided a specific example: "Data collected in 1996 from tobacco cured in one of Hassell Brown's indirect fired barns, which was heated with a heat exchanger, revealed that flue-cured tobacco cured in this barn *had undetectable levels of TSNA*s." J.A. at 6306 (emphasis added).

We conclude that this interrogatory response, which Star disclosed to the PTO, contained the critical information that the prior art had achieved low to insignificant levels of TSNA, and that the information contained in the Burton letter and in the Curran data would therefore have been cumulative in the '401 prosecution by the time the Banner lawyers were made aware of them in June 2002.

Because cumulative information is not material, we hold that the district court clearly erred in finding that the information contained in the Burton letter and in the Curran data was material to the prosecution of the '401 patent. Under these circumstances, the finding of inequitable conduct with respect to the '401 patent must also be set aside. Therefore, we reverse the judgment of unenforceability of both the '649 and '401 patents.

B. Indefiniteness

Though we reverse the district court's holding of inequitable conduct, its judgment of no liability for infringement may still be affirmed if we uphold the district court's grant of summary judgment as to claim indefiniteness because it covered all asserted claims of both patents. We review both a district court's grant of summary judgment and a holding of claim indefiniteness de novo. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). The district court held that the term "anaerobic condition" is indefinite and thus, since it appears in every asserted independent claim, held that all asserted claims are invalid as indefinite. *Indefiniteness Order*, slip op. at 12–14. However, because the claim term "anaerobic condition" is not indefinite, we also reverse the grant of summary judgment.

The requirement of claim definiteness is set forth in 35 U.S.C. § 112, ¶ 2, which requires claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." We have held that "[o]nly claims not amenable to construction or insolubly ambiguous are indefinite." *Datamize*, 417 F.3d at 1347 (citations omitted). A claim term is not indefinite just because

“it poses a difficult issue of claim construction.” *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Rather, the standard is whether “the claims [are] amenable to construction, however difficult that task may be.” *Id.* “By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of patent validity” *Id.*

The parties do not dispute the claim constructions reached by the district court, and the district court did construe all terms relevant to this appeal. In and of itself, a reduction of the meaning of a claim term into words is not dispositive of whether the term is definite. *Halliburton Energy Serv., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008). And if reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness. *See id.* at 1249–51.

The district court construed the term “anaerobic condition” to mean “an oxygen deficient condition (such as is created by an atmosphere of combustion gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity.” *Markman Order*, slip op. at 1–2. Thus, a skilled artisan would know that the claim term contemplates only conditions where the dearth of oxygen promotes the activity of the nitrate reductase enzyme. It is undisputed that those of ordinary skill would understand from the patents’ specifications that the significance of nitrate reductase activity to the claimed invention is that it

produces nitrites, which then form TSNA's. *See* '649 patent col.7 ll.39-55; '401 patent col.7 ll.43-59. Therefore, from the claim term "anaerobic condition" and the intrinsic record, a skilled artisan would discern that the term delineates those conditions where the shortage of oxygen results in increased TSNA formation. This is further supported by statements to that effect in the patents' specifications. *See, e.g.*, '649 patent col.4 ll.36-39 ("For example, it is postulated that if the conditions [contemplated for the present invention] are made aerobic, the microbes will consume oxygen in the atmosphere for their energy source, and therefore no nitrites will form.").

We have stated that "[w]hen a word of degree is used . . . the patent's specification [must] provide[] some standard for measuring that degree" to be definite. *Datamize*, 417 F.3d at 1351 (quoting *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984)). Here, the term "anaerobic condition" is in effect a term of degree because its bounds depend on the degree of oxygen deficiency. And as the district court determined in its claim construction, the intrinsic record provides a standard for measuring that degree and assessing the bounds of "anaerobic condition" as required by *Datamize*, namely the level of TSNA formation. In fact, the claims explicitly refer to the standard, requiring that the tobacco be cured in a "controlled environment" that prevents an "anaerobic condition" in order to "substantially prevent the formation of at least one nitrosamine." *See* '649 patent cl.4.

The district court further determined that TSNA formation is itself a well-defined standard as disclosed by the asserted patents. It construed the

term “substantially prevent the formation of at least one nitrosamine” to mean “the level of at least one of the nitrosamines falls within the following ranges: less than about 0.05 mg/g for NNN, less than about 0.10 mg/g for NAT plus NAG, and less than about 0.05 mg/g for NNK.” *Markman Order*, slip op. at 2. In other words, the district court was able to discern from the intrinsic record that TSNA formation, as contemplated by the asserted patents, is tied to highly specific measurements of four very specific chemical compounds. Far from being insolubly ambiguous, a skilled artisan could determine whether an “anaerobic condition” was present—or, rather, was prevented—simply by measuring the levels of NNN, NAT, NAG, and NNK.

The district court’s contrary conclusion was based on its misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process.¹² But we disclaimed any such approach in *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005). We explained that Stratagene, in making a

¹² The district court misunderstood our decision in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383–84 (Fed. Cir. 2003). There, we rejected a proposed construction that, if adopted, would have rendered the term indefinite because a given composition could both infringe and not infringe simultaneously. We did *not* hold the claim term at issue to be indefinite; in fact, after rejecting that proposed construction, we arrived at the correct construction which did not render the term indefinite. *Id.* at 1384. And while we emphasized that a claim is indefinite if a skilled artisan cannot determine if an accused product infringes or not, we did *not* hold that the infringement determination must be able to be made at any particular time.

similar argument, was “really talking about the difficulty of avoiding infringement, not indefiniteness of the claim.” *Id.* “The test for indefiniteness does not depend on a potential infringer’s ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention.” *Id.* (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005)); *see also Datamize*, 417 F.3d at 1354 (holding that “indefiniteness does not depend on the difficulty experienced by a particular person in comparing the claims with the prior art or the claims with allegedly infringing products or acts”). As construed by the district court, the term “anaerobic condition” clearly delineates the bounds of claim scope and thus is not indefinite. The district court’s grant of summary judgment of indefiniteness must therefore be reversed.

CONCLUSION

For the reasons provided above, we reverse the district court’s judgment of unenforceability of both asserted patents due to inequitable conduct. We also reverse the district court’s grant of summary judgment of invalidity of all asserted claims due to indefiniteness and remand for further proceedings on the infringement complaint consistent with this opinion.

REVERSED and REMANDED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

STAR SCIENTIFIC, INC.	*
Plaintiff	*
vs.	* CIVIL ACTION
R.J. REYNOLDS TOBACCO	* NO. MJG-01-1504
COMPANY, et al.	*
Defendants	*
* * *	* *
	*

JUDGMENT ORDER

On January 19, 2007, the Court issued its Memorandum and Order Re: Indefiniteness granting summary judgment to Defendants, but withheld the entry of Judgment pending decision of Defendants' Inequitable Conduct defense. The Court has, this date, issued its Memorandum of Decision Re: Inequitable Conduct.

Accordingly:

1. Judgment shall be, and hereby is, entered in favor of Defendants R.J. Reynolds Tobacco Company, *et al.* against Plaintiff Star Scientific, Inc. dismissing all claims, with prejudice, with assessable costs.
2. This Order shall be deemed to be a final judgment within the meaning of Rule 58 of the Federal Rules of Civil Procedure.

SO ORDERED, on Tuesday, June 26, 2007.

/ s /
Marvin J. Garbis
United States District Judge

United States District Court, D. Maryland.

STAR SCIENTIFIC, INC. Plaintiff

v.

R.J. REYNOLDS TOBACCO COMPANY, et al.

Defendants

No. Civ.A. MJG-01-1504.

June 26, 2007.

Richard McMillan, Jr., Jonathan H. Pittman, Kathryn D. Kirmayer, Mark Michael Supko, Crowell and Moring L.L.P., Washington, DC, for Plaintiff. Richard A. Kaplan, Ralph J. Gabric, K. Shannon Mrksich, Jerold A. Jacover, Cynthia A. Homan, Harold V. Johnson, Dominic P. Zanfardino, Laura Beth Miller, Christopher M. Dolan, Howard S. Michael, Jeffry M. Nichols, Robert G. Pluta, Justin B. Rand, Amanda M. Miller, Julie L. Leichtman, Andrea L. Evensen, Scott A. Timmerman, Brinks Hofer Gilson & Lione, Chicago, IL, August J. Borschke, R.J. Reynolds Tobacco Co., Winston-Salem, NC, Barry Jay Rosenthal, Bromberg Rosenthal, Rockville, MD, for Defendants.

*MEMORANDUM OF DECISION RE:
INEQUITABLE CONDUCT*

GARBIS, J.

These cases, consolidated for trial of Defendant's inequitable conduct defense, were tried before the Court without a jury.

The Court has heard the evidence, reviewed the exhibits, considered the materials submitted by the parties, and had the benefit of the arguments of counsel. The Court now issues this Memorandum of Decision as its findings of fact and conclusions of law in compliance with Rule 52(a) of the Federal Rules of

Civil Procedure.¹ The Court finds the facts stated herein based upon an evaluation of the evidence including the credibility of witnesses and the inferences which the Court has found reasonable to draw from the evidence.

I. *BACKGROUND*

A. *Procedural Setting*

Plaintiff Star Scientific, Inc. ("Star") is the exclusive licensee² of United States Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent") (collectively, "the Patents-in-Suit"), relating to the curing of tobacco. At all times relevant hereto, Defendants R.J. Reynolds Tobacco Company, a North Carolina corporation and R.J. Reynolds Tobacco Company, a New Jersey corporation (collectively, "RJR"), have been engaged in the business of producing tobacco products, including cigarettes.

On May 23, 2001, Star sued RJR (Case No. MJG01-1504), claiming infringement of claims 4, 12, and 20 of the '649 patent. On July 30, 2002, Star sued RJR (Case No. MJG-02-2504) for infringement of claim 41 of the '401 Patent. In each case, RJR counterclaimed seeking a declaratory judgment establishing non-infringement and invalidity. RJR denies infringement and asserts that the Patents-in-

¹ "In all actions tried upon the facts without a jury . . . the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58." Fed.R.Civ.P. 52(a).

² The original assignee of the Patents-in-Suit, Regent Court Technologies, granted Star an exclusive license which included the right to bring legal action to enforce the Patents-in-Suit.

Suit are invalid and/or unenforceable due to indefiniteness and inequitable conduct.

On January 19, 2007, the Court issued its Memorandum and Order Re: Indefiniteness [Document 704], granting summary judgment to RJR on the issue of indefiniteness, but deferred its entry of judgment pending decision on the consolidated trial of RJR's inequitable conduct defense.

B. Industry Setting

1. Tobacco Curing Methods

Tobacco that is freshly harvested must be "cured" before it can be used for cigarettes and other products. Essentially, "raw" tobacco is dried in a curing barn without exposure to rain or direct sunlight:

In practice, tobacco leaves are generally cured according to one of three methods. First, in some countries, such as China, a variation of the flue curing process (described below) is still being used on a commercial scale to cure tobacco leaves. Specifically, this variation of the flue curing process features the use of a heat exchanger and involves the burning of fuel and the passing of heated air through the flue pipes in a curing barn.

'649 Patent, Col. 2 ll. 53-54.³ In this first method, there is no contact between the exhaust gases and the tobacco and curing takes place in what is referred to as an "indirect fire" barn.

³ Both Patents-in-Suit make the same statements in regard to curing methods. Accordingly, citations to the '649 Patent will suffice here.

A second method, in which exhaust gases come into contact with the tobacco, takes place in what is referred to as a "direct fire" barn:

For more than twenty years, the heat exchanger method described above has been supplanted in the U.S. with [a second method,] the so-called "flue curing" method [using a propane burner]. This process involves placing the tobacco leaves in a barn and subjecting the leaves to curing with the application of convective heat using a hot gaseous stream that includes combustion exhaust gases. When convective heat is used to dry the tobacco leaves, the combustion exhaust gases (including carbon monoxide, carbon dioxide, and water) are passed directly through the tobacco.

Id. at Col. 3 ll. 4-14.

There is a third method of curing tobacco known as "air curing":

This process involves placing the tobacco leaves in a barn and subjecting the leaves to air curing without controlling the ambient conditions (e.g. air flow through the barn, temperature, humidity, and the like) and without the application of any heat.

Id. at Col. 3 ll. 19-24.

2. *Nitrosamines-TSNA*

By about the 1990's, those working in the tobacco industry became aware of a possible problem regarding the formation of nitrosamines in the curing process. Nitrosamines are nitrogen-containing chemical compounds that form in plants. The nitrosamines that form in tobacco plants during the curing process are referred to as "tobacco specific

nitrosamines" ("TSNAs"). Some TSNAs were thought to be carcinogenic. Accordingly, those in the tobacco industry sought to find ways to avoid TSNA formation in the curing process.

Persons connected with Reserca, a Swedish research company also known as "Swedish Match," came to believe that the TSNAs that were found in air-cured tobacco were caused by microbes (micro-organisms). By approximately 1993, Swedish Match had developed a method whereby the formation of TSNAs was prevented in brown tobacco (a sub-category of burley tobacco).

Swedish Match sponsored Professor Harold Burton ("Burton"), an agronomy professor at the University of Kentucky, to assist with research regarding TSNA formation. Burton published a paper in 1995 discussing a method for substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant. He concluded that this could be done by drying uncured tobacco in a combustion gas free environment and substantially preventing an anaerobic condition around the plants by controlling at least one of three curing conditions, humidity, temperature, and airflow.

At about the same time that Swedish Match was researching nitrosamines in air-cured tobacco, RJR, under the direction of Dr. David Peele ("Peele"), began researching the causes of nitrosamine formation in Virginia tobacco. RJR's research indicated that the primary reason for TSNA formation in Virginia flue-cured tobacco was not the presence of microbes, but instead the fact that exhaust gases came in contact with the tobacco. He found that old indirect-fire barns that had utilized heat exchangers and prevented exhaust gases from

coming into contact with tobacco yielded substantially lower levels of TSNA than the newer direct-fire barns.

In late 1997 or early 1998, RJR disclosed some of its work to scientists at Swedish Match as well as to Burton. Later, in approximately May or June of 1998, Peele discovered that the particular component of the combustion exhaust gases which was the primary cause of TSNA's forming during the curing of Virginia tobacco was nitric oxide.

3. *RJR (Peele)-Curing Operations*

Beginning in August of 1998, Peele experimented with the curing of tobacco in indirect-fire barns to prevent the exposure of tobacco to nitric oxide. He discovered that tobacco that was cured by this method had low to undetectable levels of at least one TSNA.

On April 26, 1999, Peele filed the patent application that led to U.S. Patent No. 6,805,134. Peele's application disclosed that if, during the curing process, the tobacco's exposure to the nitric oxide found in combustion exhaust gases is minimized, the formation of TSNA's is substantially prevented. Peele's application also disclosed means by which direct-fire barns could be converted into indirect-fire barns to prevent tobacco exposure to nitric oxide during the curing process.

In 1999, RJR contracted with certain farmers to have them provide tobacco cured in barns retrofitted with heat exchangers purchased from Vencon-

Varsos,⁴ a Greek company, and assembled and installed in the farmers' barns by Evans Machinery and Metal Fabrication, a U.S. company.

By the summer of 1999, these farmers had cured tobacco with low TSNA levels. In November 1999, RJR spent over \$11,000,000 to purchase 2050 heat exchangers and retrofit hundreds of curing barns to use this technology. RJR contracted with many farmers to provide tobacco cured in barns utilizing this heat exchanger technology for the 2000 curing season.⁵ In early 2001, RJR replaced many of the 2000 season curing contracts with new agreements that were utilized in the 2001 season and thereafter.

4. *Patents-in-Suit Filings*

The following is the chronology of the Patent Office filings pertinent to the Patents-in-Suit:

The '649 Patent

9/15/98	Application No. 60/100,372 (the "Williams Provisional Application") filed.
9/15/99	Application No. 09/397,018 (the "Williams Non-Provisional Application") filed.
3/20/01	Patent No. 6,202,649 issued.

The '401 Patent

9/25/00	Application No. 09/688,144 filed
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⁴ Vencon-Varsos adapted technology whereby heat exchangers could be utilized in virtually any existing bulk tobacco barn, enabling conversion from direct-fire to indirect-fire barns.

⁵ Some of the farmers owned their own heat exchangers while others used heat exchangers provided by RJR.

as a continuation of the Williams Non-Provisional Application”) filed.

7/30/02

Patent No. 6,425,401 issued.

II. *LEGAL FRAMEWORK*

A. *The Duty of Candor*

“Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). It is well established that:

[T]he duty to disclose information material to patentability rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application.

Id. at 1178 n. 6

Moreover, “[t]he duty of candor extends throughout the patent’s entire prosecution history.” *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803 (Fed. Cir. 1990). Accordingly: “[i]n determining inequitable conduct, a trial court may look beyond the final claims to their antecedents.... [A] breach of duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.” *Id.* at 803-04. “The duty to disclose material information extends to information such

individuals [covered by 37 C.F.R. § 1.56] are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof." Manual for Patent Examining Procedure ("MPEP") § 2001.06 (8th ed. Rev. 5, 2006).

B. *Inequitable Conduct*

"A breach of [the] duty [of candor] may constitute inequitable conduct." *Purdue Pharma. L.P. v. Endo Pharma. Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006).

As stated by the United States Court of Appeals for the Federal Circuit: "inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Espeed, Inc. v. Brokertec USA*, 480 F.3d 1129, 1135 (Fed. Cir. 2007) (quoting *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005)); *Molins PLC*, 48 F.3d at 1178. "[I]nequitable conduct requires not [merely] intent to withhold, but rather intent to deceive." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). "The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence." *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006)." The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001) (internal citation omitted).

1. *Materiality*

The PTO Regulations state, with regard to materiality:

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with the other information a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the [Patent] Office, or (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. The Federal Circuit recognizes several different standards of materiality. The first is the "objective but for" standard, "where the misrepresentation was so material that the patent should not have issued." *Digital Control*, 437 F.3d at 1315. A second test, the "subjective but for" test, finds materiality "where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so." *Id.* Lastly, the "but it may have" standard finds materiality "where the misrepresentation may have influenced the patent examiner in the course of prosecution." *Id.* The Federal Circuit has stated:

In addition, in 1977, the PTO amended Rule 56 to clarify the duty of candor and good faith before the PTO. That version of Rule 56 required applicants to disclose "information they are aware of which is material" stating that information is material "where there is a substantial likelihood that a reasonable examiner would consider it

important in deciding whether to allow the application to issue as a patent.” 37 C.F.R. § 1.56 (1977).

* * *

Even though the PTO’s “reasonable examiner” standard became the dominant standard invoked by this court, in no way did it supplant or replace the case law precedent.

* * *

However, because a party alleging inequitable conduct need only prove a “threshold level” of materiality in order to proceed to the second “balancing” portion of the inequitable conduct inquiry, and because the PTO’s “reasonable examiner” standard was broader than the other three standards, the PTO standard gradually became the sole standard invoked by this court.

Digital Control, 437 F.3d at 1315.

The Federal Circuit expressed in *Espeed* that “under the reasonable examiner standard, information is material when ‘a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.’” *Espeed, Inc.*, 480 F.3d at 1136, (quoting *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1397 (Fed. Cir. 1986)). However, it is not necessary for materiality that the disclosure of the information would have resulted in disallowance of the patent. *Li Second Family LP v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000) (stating that “information concealed from the PTO may be material even though it would not invalidate the patent.”).

2. *Intent to Deceive*

To satisfy the intent to deceive element of inequitable conduct, “the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Espeed, Inc.*, 480 F.3d at 1137-38 (quoting *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc* in relevant part)). The intent to deceive need not be proven by direct evidence; in fact, “it is rarely proven by such evidence.” *Espeed, Inc.*, 480 F.3d at 1138. The intent to deceive may be “inferred from the facts and circumstances surrounding the applicant’s overall conduct.” *Impax Labs. v. Aventis Pharms.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006) (citing *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989)).

Although intent may be found based on either direct or circumstantial evidence, the intent to deceive cannot be inferred solely from the fact that material information was not disclosed. *Braun Inc. v. Bynamics Corp. of Am.*, 975 F.2d 815, 822 (Fed. Cir. 1992). “[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.” *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990).

3. *The Balancing Test*

The Court, after finding that a false statement or omission was made in the course of patent prosecution, must determine the extent to which the conduct was material and intentional. “The court’s final step in the determination of inequitable conduct is a balancing of the degree of materiality against the degree of intent to deceive.” *Union Oil*

Co. of Cal. v. Atlantic Richfield Co., 34 F.Supp.2d 1208, 1212 (C.D. Cal. 1998). "This balancing process considers all the evidence, including that of the patentee's good faith." *Id.* (citing *Molins PLC*, 48 F.3d at 1181).

Where an omission or misrepresentation is "highly material, less evidence of intent will be required in order to find that inequitable conduct has occurred." *Espeed, Inc.*, 480 F.3d at 1135 (quoting *PerSeptive Biosystems, Inc. v. Pharmacia Biotech*, 225 F.3d 1315, 1319 (Fed. Cir. 2000)). Ultimately, the "conclusion that a patent is unenforceable is an equitable decision committed to the discretion of the district court." *Espeed, Inc.*, 480 F.3d at 1135; see *Flex-Rest, L.L.C. v. Steelcase, Inc.*, 455 F.3d 1351, 1357 (Fed. Cir. 2006).

III. DISCUSSION

A. Introduction

As discussed more fully herein, the actions of Patentee Johnnie Williams ("Williams") and others participating in the prosecution of the Patents-in-Suit constitute a substantial failure to meet the duty of candor vis-a-vis the Patent and Trademark Office. Williams and others deliberately misled the PTO in a material manner by keeping from the PTO the critical fact known to Williams and others that the claimed beneficial result – tobacco with low to undetectable TSNA levels – *had been achieved in the United States* prior to the application that led to the Patents-in-Suit.

A letter written by the patentee's technical consultant, Professor Burton (the "Burton Letter") to the patent attorney drafting the initial application, was a focus of the evidence at the inequitable

conduct trial. It was RJR's discovery of this letter that provided clear proof that Williams, the prosecuting patent attorney and others, had been aware that low and undetectable levels of TSNA had been achieved under the prior art. The Burton Letter establishes that they knew that the alleged invention did not, for the first time, enable curing of tobacco with low levels of TSNA. Rather, the benefit that could be claimed from the alleged invention would be, at most, to teach a method that might permit some degree of confidence that a curing operation could produce tobacco with low levels of TSNA. As discussed more fully herein, the Burton Letter provides evidence of the knowing material failure to disclose, but RJR's inequitable conduct proof is not limited to the document itself.

Counsel for Star, Randy McMillan, admitted in final argument that Williams and patent counsel had, at all pertinent times, been fully aware that, prior to the alleged invention, tobacco could be, and had been, cured in the United States in a process that yielded low to undetectable levels of TSNA:

MR. MCMILLAN: I think everyone involved on the patent side had the belief that, in an uncontrolled environment, it's the very nature of an uncontrolled environment, that you can get it in some uncontrolled way. You can get uncontrolled results in some uncertain.

THE COURT: You can get undetectable TSNA's?

MR. MCMILLAN: Yes, Your Honor.

Tr. 1109.⁶

⁶ References to "Tr." are to the trial transcript.

Even with this belief on the part of Star, Williams, his patent attorney, and "everyone involved on the [Star] patent side," the application leading to the Patents-in-Suit falsely stated that:

[I]t has been determined that [the prior art] as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Pl.'s Ex. 9 (hereinafter cited as "Provisional Application") at 3.

This statement in the Provisional Application was designed to mislead the PTO into believing that the prior art could not yield tobacco with low levels of TSNA. There had been no determination of the type claimed. Yet, the PTO was led to believe that the alleged invention enabled the achievement of low-TSNA tobacco for the first time. The purported "determination" on which Williams (and his attorney who relied upon Williams⁷ based the statement, did not even relate to tobacco grown in the United States. As Williams admitted at trial:

Q. So you were the person that told Mr. Delmendo to say, to say in the provisional application that when this old flue-curing process is used in the United States, that you get high levels of TSNA?

[Williams:] Yes.

Q. And you told him that, notwithstanding the fact that in the Burton letter, Professor Burton said that you get low TSNA; is that right?

[Williams:] That's true. But I'm saying if you practiced that in the United States, you won't—you won't get low levels of TSNA, because in

⁷ Tr. 422.

Brazil, where most of our tobacco comes from, that's what they do, and the levels are high.

Q. So you—

[Williams:] That was the basis for me saying that.

Q. The basis for your discussion here in the provisional about what goes on in the United States was based on what goes on in Brazil; is that your testimony?

[Williams:] Yes. Which is either the first or the second largest supply of flue-cured tobacco to America.

Q. You also based that statement on a complete absence of data for a curing done in the United States; is that correct?

[Williams:] Well, did I make a stretch from Brazil to the United States? Yes, sir. But I made that stretch with the third largest tobacco company in the United States information, that that tobacco was very similar and near identical to what is grown in Virginia with the same conditions. So did I make a stretch from Brazil to here? Yes.

Tr. 422-23.

This "stretch" kept the PTO from knowing that, as Williams knew, cured tobacco with low levels of TSNA had been achieved in the United States with tobacco grown in the United States. It is substantially likely that knowledge that the prior art could—albeit not every time—achieve low levels of TSNA would have affected a reasonable PTO examiner's evaluation of the claims at issue in the instant case. The materiality of the omission is particularly strong because of the absence of a specification of precisely how one practicing the

alleged invention is to obtain the purportedly assured result.⁸

B. The Burton Letter

As noted above, Professor Burton assisted Swedish Match with research regarding TSNA formation and published a paper in 1995 based upon his research. Sometime prior to August 27, 1998, Burton was engaged as a technical consultant for Williams with regard to a planned application for a patent relating to a tobacco curing process.

On August 27, 1998, Romulo Delmendo ("Delmendo"), a patent attorney at Sughrue Mion Zinn MacPeak & Seas ("the Sughrue firm"), was contacted by Star and asked to prepare a patent application for Williams. On August 28, 1998, Burton sent the Burton Letter at Williams' request to Delmendo to aid the patent lawyer in preparation of the planned patent application. Because of its significance, a substantial part of the Burton Letter is set forth below:

Tobacco specific nitrosamines (TSNA) are formed primarily during the curing process. I have observed that TSNA in cured tobacco leaf are [sic] dependent on the accumulation of nitrite in the leaf during curing. I have been postulated [sic] that nitrite accumulates during curing by the reduction of nitrate. Nitrite accumulates during the death of the cell and experimental evidence indicates that it is formed by the micro flora on the surface of the leaf. It must be noted that for the micro flora to reduce nitrate to nitrite

⁸ See Memorandum and Order Re: Indefiniteness [Document 704].

conditions should be approaching anaerobic (oxygen deficient) conditions. If conditions are aerobic, the microbes will use the oxygen in the atmosphere for their energy source. If the curing in a micro climate is aerobic then no nitrite will form. The curing process is certainly more complex than this explanation but it should give a thumbnail sketch on what is happening during curing.

I was in China for two weeks during 1997 and I was given commercial Chinese cigarettes. I brought some of them back to the U.S. and decided to analyze them for TSNA. To my surprise I could not detect TSNA or when I did they were very low. We analyzed at least five different commercial cigarettes and the [sic] were the leading cigarettes in China. These cigarettes were made of only flue cured tobacco and are more like the cigarettes manufactured in England. China does not import any tobacco and therefore it was all grown in China. Since China is a developing country, *they are still use [sic] the old curing technology that was abandoned in the U.S. during the sixties. It seemed to me that the probable cause for the absence of TSNA was their use of the old flue-curing techniques.* This technique uses burning fuel and passing the hot gasses through flue pipes in the curing barn. Therefore, tobacco in the old barns were exposed to radiant heat. The modern curing barns are different since the fuel source (propane) is combusted and the exhaust is passed directly through the tobacco. This can create anaerobic condition [sic] since the oxygen in the atmosphere is depleted by combustion and the combustion gases (carbon dioxide and water) are

not aerobic. During curing, the tobacco leaf also emits carbon dioxide and will dilute the oxygen further.

Defs.' Ex. 53 (hereinafter cited as "Burton Letter") (emphasis added).

It is important to note, at the threshold, that the significance of the Burton Letter—in context—is that Burton affirmatively stated to Williams that he attributed the low levels of TSNA found in the Chinese cigarettes to the use of the indirect fire flue-curing process *that had previously been used in the United States*. It is of no moment whether the practice in China constituted prior art. The significance is that the Burton Letter reveals that he knew, and informed Williams and Delmendo, that the prior art *practiced in the United States* had been able to achieve tobacco with low to undetectable levels of TSNA.

C. *The 1998 Provisional Application*

Patent counsel (Delmendo) and Williams were aware from the Burton Letter that Burton had obtained cigarettes in China that had low or non-existent levels of TSNA. Moreover, Burton had stated that "the probable cause for the absence of TSNA [in the Chinese cigarettes] was their use of the old flue-curing techniques" formerly used in the United States. Burton Letter at 1.

Nevertheless, the Provisional Application did not reveal even the possibility that the old curing method could produce low levels of TSNA. Rather, the Provisional Application stated:

In some countries, such as China, an older version of the flue curing process (hereinafter discussed in detail) is still being used on a

commercial scale to cure tobacco leaves. Specifically, this particular flue curing process involves the burning of fuel and the passing of the hot combustion exhaust gases through flue pipes in a curing barn. Accordingly, in this process, primarily radiant heat emanating from the flue pipes is used to cure the tobacco leaves. *It has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.*

Provisional Application at 2-3 (emphasis added).

Not only was the PTO not informed that low levels of TSNA had been obtainable, but there was no adequate basis for the statement of a "determination" that the process applied to United States-grown tobacco yields high levels of TSNA. This "fact" did not come from Burton. As he testified at his deposition:

[Burton:] Let me repeat the question that I think I heard. After August 24, 1998, did I ever tell anyone that if you use the old-the Chinese, the old flue-curing process, that we would get high levels of nitrosamines?

No, not specifically that I'm aware of, I ever told anybody that.

Q. Do you recall ever telling Mr. Delmendo that?

[Burton:] No.

* * *

Q. And as you sit here today, though, you can't recall ever, after the date of this letter, Exhibit 53, informing anyone that it was your view that use of this, what you refer as this old flue-curing

technique, in the U.S., flue-cured tobacco, would result in high nitrosamines?

[Burton:] I'm not aware of it.

Q. And as you sit here today, you certainly don't recall telling Mr. Delmendo that?

[Burton:] No.

Burton Dep. 24:10-24:20, 25:15-25:24, Jan. 22, 2003.

As noted above, Williams "stretched" to transform some kind of information relating to the curing of Brazilian tobacco into a "determination" as to what would result with tobacco grown in the United States.

Prior to filing the Provisional Application, Williams obtained some samples of cured tobacco from old indirect-fired barns in the United States, as well as data referred to as "the Curran data" and "the Jennings data." Plaintiff has been unable to provide this data. The Court finds from the evidence presented at trial that the Curran data would have indicated that tobacco cured in an oil-fired barn with no exhaust had low TSNA levels, 0.39 parts per million ("ppm"), and the Jennings data indicated a level of TSNA of 1.5 ppm in tobacco cured in indirect-fired barns. *See* Tr. 436, 439 (testimony of inventor Williams as to the contents of the Curran and Jennings data); *id.* at 606 (testimony of Defendants' expert Dr. Otten that the Curran data reflected TSNA levels of 0.39 ppm). These data were not disclosed to the Patent and Trademark Office. While the weight to be given this data might be debated, the Court finds that the information should have been provided to the PTO for the examiner's consideration-particularly in a context in which Star's patent counsel failed to disclose even that the

prior art had been capable of achieving low-TSNA tobacco.

After filing the Provisional Application, Delmendo called Williams on September 18, 1998. Delmendo's notes from that conversation indicate that there remained a "prior art concern" Tr. 95. Delmendo testified that the "prior art concern" was that the indirect heat exchange method ("the oil-type barn with the airflow natural heat sucked in from the side has a fan in it") produces tobacco with "very low" nitrosamine levels. *Id.*; *see id.* at 94-98. Since the Provisional Application did not disclose that the prior art could achieve such low levels of TSNA, Delmendo felt "concern" as to whether the information should be disclosed in an Information Disclosure Statement ("IDS") or in the patent specification, as the information might be important to the Patent Office. *Id.* at 97. However, the PTO was not informed that the prior art was at least capable of yielding TSNA levels as low as that purportedly yielded by practice of the alleged invention. Moreover, as noted below, the concern on the part of Delmendo was not communicated to, indeed, affirmatively kept from, his successor patent counsel after he was discharged by Star.

D. The 1999 Non-Provisional Application

The statement in the Provisional Application that "[i]t has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA" was removed by Delmendo for the 1999 Non-Provisional Application. Nevertheless, the Non-Provisional Application that was ultimately filed still did not reveal that the prior art could yield low levels of

TSNA. Instead it "danced" around the matter, stating:

[T]his [old] process does not appreciate, and does not provide for, controlling the conditions within the barn to achieve prevention or reduction of TSNA's. This technique has been largely replaced in the United States by a different flue-curing process.

Pl.'s Ex. 11 (hereinafter cited as "Non-Provisional Application") at 4.

Delmendo did not provide a reason why the "determined" language had been replaced:

Q. And this was a change from the language that we talked about earlier today, from the provisional application that had made reference to the high TSNA levels?

A. Yes. This, now, that sentence was not deleted, because I felt that it was incorrect. I still believe that sentence to be correct in substance. *But for whatever reason*, it was replaced with this language, which is a correct characterization of the differences between the claimed invention and the prior art.

Tr. 101 (emphasis added).

Delmendo stated that the words "the process does not appreciate" were used in reliance on information provided by Williams and a technical advisor, Mr. O'Donnell:

Q. And is it true that you relied on Mr. Williams and Mr. O'Donnell as the source of that information?

A. Yes. We were advised that in the prior art they threw in tobacco into the curing barn without any

regard for reducing TSNAs, whereas in the claimed invention, what we were doing, or what the inventor was doing, was to determine and select one or more of the specified conditions in order to ensure the reduction and prevention of TSNAs.

Tr. 102.

The record confirms that Williams and patent prosecution counsel were well aware throughout the PTO process that the prior art had been capable of providing low-TSNA tobacco and that the purported benefit of the alleged invention was to enable one to "ensure the reduction and prevention of TSNAs." *Id.* The PTO was not, however, candidly and clearly informed of this, but was led to believe that the prior art could not achieve tobacco with low levels of TSNA.

E. The Firing and Quarantine of Delmendo and his firm

Just two days after the Non-Provisional Application was filed, Star discharged Delmendo and the Sughrue firm. Tr. 103. Paul Rivard ("Rivard") and the law firm of Banner & Witcoff ("the Banner firm") were hired to replace Delmendo and the Sughrue firm in representing Williams during the remaining prosecution of the Patents-in-Suit. *Id.* at 126.

There was no contact between the two firms, even for the purpose of effecting a turnover of the pertinent files. *See id.* at 104, 380. Instead, Scott Flicker, a lawyer from Paul Hastings—the law firm of Star's Chairman, Paul Perito—acted as a "prophylactic intermediary" to transfer the files between the two firms. *See id.* at 375-81. Flicker

testified that he was a liaison, physically transporting files from the Sughrue firm to the Banner firm and acted as a communication conduit between the two firms, but never set up a meeting between the Banner and Sughrue firms. *See id.* No plausible reason has been presented for this course of action other than the obvious one—to keep the Banner firm from learning what the Sughrue firm knew and thought.

The Court finds, upon evaluation of the credibility of witnesses and inferences from the evidence, that isolation of the Banner firm from predecessor counsel was part of an intentional effort to avoid “tainting” the Banner firm with Delmendo’s knowledge and concerns about disclosures to the PTO. The change of counsel was arranged so as to “insulate” replacement patent counsel from Delmendo and the Sughrue firm.

There is a question as to whether the Burton Letter was included in the Sughrue firm files that were turned over to the Banner firm. Rivard could not testify as to whether or not the Burton Letter was, in fact, in the Sughrue firm file that was delivered to him. He testified:

[Rivard:]. . . Initially, when we had received the file, I had it put into a Banner Witcoff folder, as you see here, essentially in the same order that we received it from the Sughrue firm. It was transferred into our file, put into our docketing system, and at that point it was sent to the file room, and I did not—I did not think to request it when I was working on the ‘649 patent.

When I went through it initially, I did go through it to see if there was any patents or articles, as I mentioned, I did not see any.

Q. So when you went through that file initially, you didn't see the Burton Letter?

[Rivard:] No, I was not making—I was not reading all the correspondence and notes. I was really just looking for patents, journal articles, things that normally would be sources of prior art.

Q. Was it in the file or not?

[Rivard:] I didn't check at that point. More recently a month or so, I went back and checked, and the Burton Letter was in the provisional file.

Q. So it's the case, sir, that the first time you went back to the provisional file to look for the Burton Letter was about a month [before the trial of the instant case]?

[Rivard:] That's correct.

Tr. 135-36.

If the Burton Letter was in the file delivered to Rivard's firm, he says he did not know it. Indeed, as discussed below, the first time he admits learning of the Burton Letter was at a meeting on June 10, 2002, convened because *RJR* had obtained the letter in discovery and was thought likely to introduce these matters in the litigation.

While a suspicious matter, the Court does not find, sufficiently to satisfy the clear and convincing standard, that someone intentionally removed the Burton Letter from the Sughrue firm file before delivery to the Banner firm. The Court does find, however, that Rivard—although consulting with Burton in the course of his work for Star—was never

told about the Burton Letter until, as noted below, after the issuance of the '401 Patent and the issuance of a Notice of Allowance of the '649 Patent. Moreover, the Court finds that had Star not prevented contact between Delmendo and Rivard, Delmendo would have communicated his knowledge and concerns about the ability of the prior art to yield low levels of TSNA and Rivard would have been told of the Burton Letter or, at least, would have adequately examined his predecessor's file to have found the Burton Letter.

The Court finds that Star, through its use of its chairman's law firm as an intermediary, "engineered" the isolation of Delmendo from Rivard so as to limit Rivard's knowledge and influence his (and his firm's) exercise of professional judgment as to the duty of candor vis-a-vis the PTO. Star cannot seek to avoid an inequitable conduct finding by relying upon an attorney whom it blocked from such consultations with prior counsel. *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, --- F.3d ---, No.2006-1517 (Fed. Cir. May 18, 2007) (stating that firms cannot insulate their attorneys "against charges of inequitable conduct by instituting policies that present [the attorneys] from complying with the law"); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001).

F. The Petition to Make Special

The first substantive patent prosecution action taken by Rivard was to file a Petition to Make Special in February of 2000. In patent prosecution practice, an applicant can file a petition to make special to request the PTO to accelerate a patent's prosecution. *See* 37 C.F.R. § 1.102 (2005); *MPEP* § 708.02.

In the context of an inequitable conduct determination, there is particular significance to a petition to make special. "[A] false statement in a petition to make special is material if ... it succeeds in prompting expedited consideration of the application." *Gen. Elec. Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994). This is so "because, by filing a petition to make special, the applicant 'requested special treatment and induced reliance on its statement that a prior art search had been conducted.'" *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 423 U.S. 1089 (1998) (quoting *Gen. Elec. Music Corp.*, 19 F.3d at 1411); see also *MPEP* § 708.02, II(5).

Rivard testified that he did not review the Sughrue file in connection with his preparation of the Petition to Make Special and the Information Disclosure Statement ("IDS") filed therewith.⁹ Tr. 135. However, he did have a meeting with several Star executives and informed them of the duty to disclose all prior art information. None of those individuals provided Rivard with the Burton Letter, the Curran data, or discussed concerns about the prior art. See *id.* at 130-32. The Petition to Make Special did not disclose that the prior art had been capable of producing low-TSNA tobacco and continued to give the impression that it was the alleged invention that, for the first time, enabled such a result.

⁹ This omission appears to be ordinary, if not gross, negligence, especially in the context in which Delmendo had been prevented from contact with his predecessor counsel. Nevertheless, even "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive. . . ." *Kingsdown Med.*, 863 F.2d at 876.

In the Information Disclosure Statement Including Discussion of References in Support of Petition to Make Special, Rivard stated: "[t]he resulting tobacco product [achieved from practice of the invention] is materially and substantially different than tobacco described in the [disclosed prior art] discussed hereinabove." Pl.'s Ex. 12, Tab E at 9. There was no disclosure that the prior art included processes that could produce low-TSNA tobacco. *See id.*

Furthermore, in the IDS, counsel stated that the prior art does not discuss nitrosamine content in cured tobacco and neither "describes [n]or suggests tobacco products comprising cured tobacco having nitrosamine content reduced by heating uncured tobacco with convection in an environment substantially free of exhaust gases or which otherwise is substantially non-anaerobic." *Id.* at 9. By so doing, counsel led the PTO to believe that the pertinent art consisted solely of publications and provided no hint (much less a candid disclosure) that there was prior art in the form of curing methods previously known and used in the United States.

The Court, evaluating the credibility of witnesses and drawing reasonable inferences from the evidence, finds that in connection with the Petition to Make Special, that even if Rivard had been unaware of the Burton Letter, he was unaware because Williams and others associated with Star intentionally kept the information from him. The Court further finds that had Rivard known of the Burton Letter, he would have disclosed it in the

Information Disclosure Statement¹⁰ and would have revealed – as plainly indicated in the Burton Letter – that the prior art had been capable of producing tobacco with low levels of TSNA. Furthermore, Rivard would not have been able to mislead the PTO into believing that the only prior art was in written form.

G. Trial Counsel Involvement

Attorneys who ultimately became trial counsel in the instant case were involved in monitoring the prosecution of the Patents-in-Suit.¹¹ However, trial

¹⁰ At trial, while not willing to concede materiality, Rivard acknowledged that he would have disclosed the Burton Letter if he had been aware of it.

Q. Because if in your view the contents of the Burton Letter aren't material, then what the heck, it's another piece, like most of the other stuff that Reynolds blew smoke about, dump it in, so I gather, I gather, that if you had the Burton Letter earlier, if you knew about it at the time you, or earlier, including the time that you did your IDS, you would have tossed the Burton Letter into [sic] because you err on the side of disclosure?

A. Yes, I expect I would have.

Tr. 302.

¹¹ As Rivard testified at trial:

Q. It's also the case, sir, that Crowell and Moring was kept apprised of the process of the prosecution of the two Patents-in-Suit?

[Rivard:] Yes. Crowell and Moring was copied of the filings made with the patent office and responses that were to be submitted to the patent office.

Q. Who did you copy at Crowell?

counsel did not believe themselves to be bound by the duty of candor. In anticipation of suit against RJR, and after suit was filed, Crowell & Moring ("the Crowell firm") monitored Patent Office filings. Nevertheless, the Crowell firm disavowed any obligation to tell the Banner firm about information it obtained that was material to the PTO. As McMillan testified:

Q. Well, let me see, I guess you're saying, then, if you became aware of information from the litigation that was material to the '401 application, you don't think you had an obligation to tell the Banner firm about it, that's what you're saying, right?

[McMillan:] Well, yeah, that's correct. I don't think that the duty of candor, you know, of a prosecuting attorney who's working on a different application extends to me.

Q. And so I just want to make sure I'm hearing this right. So you're one of the primary liaisons between the Crowell firm and the Banner firm; and it is your testimony, sir, that if you became aware of information material to the '401 patent application, you did not believe you had an obligation to make that information available to the Banner firm; is that your testimony?

[McMillan:] That is my testimony, yes.

Tr. 307-08. McMillan further testified:

Q. And your testimony, sir, is that you personally do not believe you would at any time have ever owed a duty of candor to the patent office in

[Rivard:] Rick McMillan.

connection with either the '649 or '401 patent application; is that right?

[McMillan:] That's my belief.

Id. at 327-28.

The Crowell firm, providing input to the Banner firm, knew of the fact that the prior art had been capable of producing low-TSNA tobacco. On October 25, 2000, McMillan wrote to Star's chairman, Paul Perito, expressing concern over the prior art and what should be disclosed:

The fact that the traditional heat-exchange curing process might have produced low TSNA leaf some of the time, and the fact that the Reynolds process *does* produce such ultra-low TSNA tobacco some of the time, raises the issue of whether the product claimed by the '905 application and the process claimed by the '018 application are novel (*i.e.*, not anticipated) as required by 35 U.S.C. § 102.

* * *

Again, because TSNA testing is fairly new, it is our belief that no one even recognized that the heat exchangers did, on occasion, result in a low-TSNA product. Accordingly, it seems fairly safe to assume that the traditional heat-exchange process does not explicitly anticipate the '018 claims.

Defs.' Ex. 239 (hereinafter cited as the "McMillan Letter") at 2, 7 (emphasis in original). The statements in the McMillan letter are significant. First, he stated that Star did not "currently know" (in 2000) whether the old process "resulted in low TSNA tobacco." *Id.* at 2. However, in the Provisional

Application filed September 15, 1998, Williams flatly stated *as a fact* that:

It has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Provisional Application at 3.

Furthermore, McMillan recognized that the fact that the old process "might have produced low TSNA leaf some of the time" would be material if known by the PTO because it would at least raise an issue as to novelty. McMillan Letter at 2.

Finally, the McMillan letter reflects the view that, because TSNA levels had not been tested until recently, there would not likely be any written "prior art" such as a patent or publication that would reveal that the old process was capable of producing low-TSNA tobacco. Therefore, the fact that the prior art could yield low-TSNA tobacco, if revealed to a reasonable PTO examiner, would be substantially likely to be considered important in regard to the evaluation of the alleged invention and the scope of any allowable claims.

It is clear that, at least as of October 25, 2000, while engaged in the patent prosecution process, and in the context of a Petition to Make Special, the Crowell firm (even if not specifically aware of the Burton Letter itself) was aware of the fact that low-TSNA tobacco could be produced by the prior art and took no steps to make this known to the Patent Office.

H. *RJR Discovers the Burton Letter*

On March 20, 2001, the '649 Patent issued. On May 23, 2001, Star filed the first of the two instant

cases, MJG01-1504, alleging that RJR infringed on the '649 Patent. Rivard continued with the prosecution of the Non-Provisional Application (leading to the '401 Patent) relying upon the Crowell firm, Star's trial counsel, to inform the Banner firm of material information.

Rivard testified at trial, confirming his deposition testimony:

[Q.] Is it fair to say that you relied on the Crowell and Moring firm to bring to your attention any material that you came across in litigation that might be relevant to the '401 patent prosecution?

[Rivard:] I think that's fair to say, that we had discussions with them along the way to make sure that we became aware of anything. . . .

[Q.] And in fact that, that was, I suspect, an expectation that you had, that if there was information that the Crowell and Moring lawyers learned of, that may have an impact on the prosecution of the '401 patent, that would be brought to your attention, correct.

[Rivard:] Yes, that was my understanding.

Tr. 170 (reading deposition of Rivard at trial).

On January 18, 2002, Rivard wrote to Star's general counsel advising of the Notice of Allowance of what became the '401 Patent. Rivard stated:

Because our duty to disclose material information to the USPTO continues up until the day the patent issues, we will need to file a supplemental information disclosure statement to cite any relevant documents that come to our attention as a result of the ongoing litigation against R.J.

Reynolds. This submission must be filed on or before the day the issue fee is paid.

Defs.' Ex. 454.

At this point, Rivard did not know of the Burton Letter, but, of course, Star did. Moreover, litigation counsel, if not aware of the Burton Letter on January 18, 2002, became aware of it shortly thereafter. In the course of discovery, RJR served a document subpoena on Burton and the University of Kentucky. In February of 2002, RJR obtained a copy of the Burton Letter. Star was then faced with the problem that RJR had the Burton Letter, but the PTO—that had not yet issued the '401 Patent—had not been made aware of the letter or the implication of its contents.

Even then, neither Star nor its litigation counsel, who—as Rivard testified—were being relied upon to provide pertinent information ascertained in the litigation against RJR, disclosed the Burton Letter or its contents to Rivard.

In May of 2002, RJR filed its Amended Answer, which included therein references to the Burton Letter and the Curran data. At that point, Star and its litigation counsel found it necessary to inform the Banner firm. This resulted in a June 10, 2002 meeting at which Rivard first saw the Burton Letter¹² and the Curran data. Some two days later, Rivard prepared a Supplemental Information Disclosure Statement he intended to file with the PTO stating, in pertinent part:

¹² According to Star, the Burton Letter had been in the Banner firm's possession—in the files of predecessor counsel—but simply not been noticed.

Pursuant to his duty of good faith and candor set forth in 37 C.F.R. §§ 1.56, 1.97, 1.98 *et seq.*, Applicant submits herewith the attached form PTO-1449. Applicant respectfully requests that the Examiner consider the documents listed [the Burton Letter and the Curran data] therein in connection with the examination the subject application. A copy of each document is attached.

* * *

Neither of these documents is believe material to patentability of the claimed invention.

* * *

Document AJ is a letter from Dr. Harold Burton to Rom Delmendo, an attorney who was involved in the initial preparation of the application. As is apparent from the first paragraph of the letter, Dr. Burton simply seeks to help explain the science involved in Mr. Williams' invention.

Defs.' Ex. 382.

The proposed IDS, while subject to debate as to the completeness of its candor, if filed, would have at least put the PTO on notice of the Burton Letter and Curran data so that the PTO could have made its own evaluation of Rivard's contentions as to materiality and significance.

On June 12, 2002, after Rivard informed trial counsel of the Banner firm's intention to make the disclosure to the PTO, a series of emails ensued among lawyers in the Crowell firm:

- June 12, 2002, 2:45 p.m.: Michael Coe ("Coe") to McMillan and other Crowell attorneys:

Paul Rivard just called. . . . Banner would like to include the Answer and Counterclaim and

possibly the supporting materials (like, for example, deposition exhibits 7 and 8) in a supplemental IDS before the Examiner in the pending applications.

* * *

I generally am inclined towards disclosure, but would like to hear your thoughts and/or instructions. Although the Amended Answer does not specifically refer to Burton's August 1998 letter and to deposition exhibits 7 and 8, we need to consider whether they should be disclosed. My initial reaction is (1) that we properly identified JW as the correct inventor and the letter is not material to patentability (which necessarily was the decision made by Sughrue Mion and Banner & Witcoff from August 1998 onwards) but (2) that deposition exhibits 7 and 8 should be disclosed out of an abundance of caution even though they may be inconclusive as to description and in any event don't demonstrate a repeatable and consistent low-TSNA process, which is the core of the claimed invention.

• June 13, 8:11 p.m.: McMillan responds to Coe and the other Crowell attorneys:

You, J.D. and Banner should decide this.

• June 13, 9:59 a.m., Michael Jacobs ("Jacobs") to Crowell attorneys Coe and Joseph Evans ("Evans"):

I think we should err on the side of disclosure, and we should do so as soon as possible. We have to eliminate any suggestion that there has been lack of disclosure during prosecution of the entire family of patents, and prompt disclosure of this material will certainly not hurt.

• June 17, 10:06 a.m.: Evans to Jacobs, Coe and McMillan:

I think Mike Jacob's [sic] comment is on target. We need to demonstrate as conclusively as we can that we have nothing to hide from the PTO and consistently follow a policy of full and prompt disclosure of all relevant information. I recommend Michael Coe give Paul the go ahead. I would like to review the IDS before it is filed, and I want to be sure that Dale Hoscheit sees it too.

Defs' Ex. 383 (emphasis added).

Thus, it appears that the Crowell attorneys, except McMillan, put in writing their view that disclosure should be made. McMillan, in writing, deferred to Coe and the Banner firm to make the decision. Nevertheless, on June 19, 2002, the Banner firm lawyers decided not to make the proposed disclosure to the Patent and Trademark Office. Tr. 180 (Rivard).

The Court finds that there was no valid justification for failing to make the disclosure as originally recommended by the Banner firm. Upon an evaluation of credibility and reasonable inferences from the evidence, the Court finds that Williams and others "leaned" on the Banner firm and that the Banner firm made an inappropriate professional decision.

Mr. Jacobs was prescient when he noted that "[w]e have to eliminate any suggestion that there has been lack of disclosure during prosecution of the entire family of patents, and prompt disclosure of this material will certainly not hurt." *Id.* Patent counsel did not eliminate the suggestion and, indeed, by their actions made it rather clear that there was a

lack of adequate candor to the PTO during the prosecution of the Patents-in-Suit.

I. Particular Credibility Concerns

Star has taken certain action in connection with this matter that does not promote reliance upon its credibility.

Professor Burton, the author of the Burton Letter, provided a Declaration to the PTO and assisted counsel in regard to the instant case. Star funded a chair at the University of Kentucky in Burton's name, paid him a retainer more than his annual salary regardless of any work product produced, and gave Burton hundreds of thousands of dollars in stock options.¹³ Tr. 555; Burton Dep. 61:5-62:17, 49:11-50:4, Jun. 26, 2002.

Star purportedly relied upon the Banner firm to make professional judgments in the prosecution of the Patents-in-Suit, including the decision not to make the disclosures here at issue. As discussed above, the Banner firm changed¹⁴ its initial decision to file an Information Disclosure Statement drafted by Rivard. There are serious questions as to the reliability of the Banner firm decisions made during its tenure as prosecutor of the Patents-in-Suit.

First, Star-without any plausible justification-prevented the Banner firm from contact with predecessor counsel. Second, Star gave the Banner

¹³ Burton has since returned any stock options received from Star.

¹⁴ The Court finds no reasonable, legitimate basis for failing to file the Supplement Information Disclosure Statement prepared and proposed by Rivard.

firm stock options with substantial potential value¹⁵ as an incentive for meeting certain "performance criteria," such as getting the patents issued by the PTO. *See* Defs.' Ex. 235. The Court finds that it cannot treat the Banner firm's decision to withhold disclosure of the data from the PTO as the exercise of disinterested professional judgment.

The Court also notes with concern the participation of McMillan and others of the Crowell firm in the patent prosecution process. McMillan was—as he had to be in view of his role in the matter—both lead trial counsel and a critical trial witness. This happenstance is particularly troubling when coupled with the substantial financial interest of both litigation counsel (the Crowell firm)¹⁶ and patent counsel (the Banner firm)¹⁷ in the issuance of the Patents-in-Suit and leads to substantial doubt as to the professional independence of both firms.

J. The Inequitable Conduct Determination

As discussed above, to establish inequitable conduct, a party defending against a patent infringement claim must prove, by clear and convincing evidence:

- (i) Affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information; and

¹⁵ The option was to buy 210,526 shares at \$2.375 per share. At trial, the stock was selling in the \$4 to \$5 range. Tr. 562.

¹⁶ *See* Tr. 337-38 (testimony from McMillan that the Crowell firm worked on a fixed-fee basis with a substantial financial incentive, based on the outcome of the case).

¹⁷ In light of the substantial amount of stock warrants the firm was given by Star.

(ii) An intent to deceive.

Espeed, Inc., 480 F.3d at 1135.

If a district court finds a threshold level of both materiality and intent to deceive, the district court must balance the evidence to determine if equity should render the patent unenforceable. *Id.* RJR has established by clear and convincing evidence each of the elements of its inequitable conduct defense.

1. *Materiality*

There is no doubt that throughout the process of prosecution of the Patents-in-Suit, Williams and others kept critical information from the PTO so as to give the false impression that, as of the time of the application leading to the Patents-in-Suit, there had been no curing processes used in the United States that was capable of producing tobacco with low levels of TSNA. The evidence clearly and convincingly establishes that, at all times during the course of prosecution of the Patents-in-Suit, everyone on the Star patent side knew that the prior art could yield low TSNA tobacco at least some of the time. That fact should have been candidly disclosed from the beginning by a straightforward statement. Even if one could argue that the Burton Letter *per se* need not have been disclosed, the essential fact revealed therein—that a curing method previously used in the United States was capable of, and indeed was the probable cause for, the production of tobacco with low to undetectable levels of TSNA—should not have been kept from the PTO. Likewise, even if the Curran and Jennings data were not, *per se*, required to be disclosed, the essential fact that the prior art could yield low levels of TSNA should have been.

The fact that the prior art was capable of producing low-TSNA tobacco was manifestly material. The alleged invention did not, as asserted by Williams in the patent prosecution, allow the production of low-TSNA tobacco *not previously obtainable at all*. Rather, to the extent that there may be held to be any invention at all,¹⁸ the invention would lie in enabling a curing process that would enable the production of low TSNA tobacco allegedly more reliably than had been possible under the prior art.

In sum, as acknowledged contemporaneously by Star's own counsel, "[t]he fact that the traditional heat exchange curing process might have produced low-TSNA leaf some of the time, raises the issue of whether the product claimed [by the applications for the Patents-in-Suit] are novel, as required by 35 U.S.C. § 102." McMillan Letter at 2 (written October 25, 2000).

2. *Intent to Deceive*

The Court finds that RJR has established the intent to deceive by Williams and others by clear and convincing evidence. They engaged in a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco. The scheme started with the false statement that "[i]t has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA," and proceeded through the entire course of prosecution in the PTO. Even after the '649 Patent had been issued, after

¹⁸ By Memorandum and Order re: Indefiniteness [Document 704], the Court has held the Patents-in-Suit invalid due to indefiniteness.

Star and counsel were aware that RJR had discovered the Burton Letter—and thus could prove knowledge of the essential fact embedded therein—and with statements from several patent attorneys in the Banner firm clearly advising disclosure, the PTO was not informed that the prior art had been capable of yielding tobacco with low levels of TSNA.

In the instant case, both Delmendo and Rivard testified—as did counsel in the recent Federal Circuit case *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*—that if they had any questions about materiality of a fact, they would disclose it to the PTO. *See* Tr. 93, 302; *McKesson*, ---F.3d ----, No.2006-1517, (Fed. Cir. May 18, 2007). In *McKesson*, the Federal Circuit considered the Eastern District of Virginia's finding of inequitable conduct. The Eastern District had found the patent attorney's actions "inconsistent with [his] assertion on the witness stand that it was his practice to be 'over inclusive' and to 'bend[] over backwards to make sure [he] got everything into the case.'" *Id.* at 17, --- F.3d at ----. Similarly, here, the actions of patent counsel were inconsistent with a purported practice of erring on the side of disclosure—an inconsistency supporting the conclusion that the failure to disclose was intentional.

In affirming the trial court, the Federal Circuit in *McKesson* noted that in spite of the advice provided to prosecuting attorneys in the 1986 version of the Manual for Patent Examining Procedure that "information . . . specifically considered and discarded as not material" ought to be "recorded in [the] attorney's file or applicant's file, including the

reason for discarding it,"¹⁹ the prosecuting attorney offered no such recorded reason for his discarding of the information; "he was only able to give speculative testimony about the conclusions he must have drawn at the time" with respect to the materiality of the information in question. *Id.* at 33, --- F.3d at ----. The *McKesson* court noted that the case before it "was not a case of mistake or negligence - the prosecuting attorney testified that he would make all the same nondisclosure decisions again if prosecuting the same applications today." *Id.* at 2, --- F.3d at ----.

In contrast, in the instant case, Rivard, who says he was not aware of the Burton Letter until after the '649 Patent had issued and after a Notice of Allowance had been issued as to the '409 Patent, testified that if he had known what Delmendo knew when filing the Provisional and Non-Provisional Applications, *he would have made the disclosure that Delmendo failed to make.* Tr. 302.

¹⁹ The full text of the 1986 version of MPEP § 2004(18) reads:

18. Finally, if information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

MPEP § 2004(18) (5th ed. Rev. 3, 1986).

Delmendo justified not disclosing Once the Burton Letter and the Curran data after he was informed at the June 10, 2002 meeting, on the basis of cost and delay in patent issuance. However, the cost would have been under \$1,000, a nominal amount in context. Moreover, the delay in issuance of the '410 Patent by no means justified nondisclosure-particularly since the '649 Patent had already issued and RJR had been sued for its infringement in the first of the instant cases. The Court does not find plausible counsel's assertions that the Banner firm made a reasonable professional decision not to make the disclosure at issue to the PTO.

The Court finds that the reason for nondisclosure in June of 2002 was concern that the PTO would, indeed, find the information material, would raise issues as to the allowance of claims and confirm RJR's position that the disclosure should have been made from the beginning of the patent prosecution process.

3. *Balancing Test*

In view of the Court's finding that RJR has proven materiality and intent by clear and convincing evidence, it must "balanc[e] the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001).

The balancing test does not present a close issue in the instant case. There is clear and convincing proof of substantial material false statements and omissions. There is also clear and convincing proof of an intent to deceive on the part of Williams and others to a seriously high degree.

The Court finds RJR to have made a strong showing of materiality and intent. The Court, therefore, concludes that it should, and shall, exercise its discretion to determine the Patents-in-Suit unenforceable by virtue of inequitable conduct before the PTO by Williams and others.

IV. *CONCLUSION*

For the foregoing reasons:

1. The Court holds U.S. Patent Nos. 6,202,649 and 6,425,401 unenforceable.
2. Judgment shall be entered by separate Order.

SO DECIDED, on Tuesday, June 26, 2007.

/ s /

Marvin J. Garbis
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

STAR SCIENTIFIC, INC.	*	
Plaintiff	*	
vs.	*	CIVIL
R.J. REYNOLDS TOBACCO	*	ACTION NO.
COMPANY, * et al.	*	MJG-01-1504
Defendants	*	(Consolidated
	*	with MJG-02-
	*	2504)

* * * * * * *

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**CORRECTED¹ MEMORANDUM AND ORDER
RE: INDEFINITENESS**

The Court has before it Defendants' Motion for Summary Judgment of Invalidity Based on Claim Indefiniteness [Paper 668], Plaintiff's Cross-Motion for Summary Judgment that all the Asserted Claims of the Patents-in-Suit are Not Indefinite [Paper 682], and the materials submitted relating thereto.

Plaintiff Star Scientific, Inc. ("Star") contends that Defendants R.J. Reynolds Tobacco Company, a North Carolina corporation and R.J. Reynolds Tobacco Company, a New Jersey corporation (collectively, "RJR"), infringed certain claims of United States Patent Nos. 6,202,649 ("the '649 Patent") and 6,425,401 ("the '401 Patent") (the

¹ The original Memorandum And Order Re: Indefiniteness [Document 704] inadvertently omitted the word "not" from the second sentence of the second paragraph under the caption "Anaerobic Condition." This omission is corrected herein.

"Patents-in-Suit") that relate to the curing of tobacco.

I. INTRODUCTION

Tobacco that is freshly harvested is not suitable for human consumption but must be "cured" before it can be used in cigarettes and other products. Tobacco has, of course, been cured for centuries by various methods, including those involving types of drying processes in "barns."

By about the 1990's, the tobacco industry became aware of a possible problem in regard to the formation of nitrosamines² in the curing process. The nitrosamines that form in tobacco plants during the curing process are referred to as "tobacco specific nitrosamines" or "TSNAs." Some TSNAs were thought to be carcinogenic, so efforts were made to find ways to avoid TSNA formation in the curing process.

In September of 1998, Jonnie Williams ("Williams") filed a Provisional Application³ and, a year later, a Non-Provisional Application.⁴ These Applications led to the issuance of United States Patent Nos. 6,202,649 ("the '649 Patent") and 6,425,401 ("the '401 Patent") (the "Patents-in-Suit"). The Patents-in-Suit include claims relating to methods of curing tobacco claiming a tobacco curing process to prevent TSNA formation comprising drying in a *controlled environment* (controlling

² Nitrosamines are chemical compounds that contain nitrogen and that form in a variety of organic materials(including plants).

³ Application Serial No. 60/100,372.

⁴ Application Serial No. 09/397,018.

humidity, temperature and/or airflow) with sufficient airflow to prevent an *anaerobic condition*.

As discussed herein, RJR asserts that the claims at issue are indefinite by virtue of the inclusion therein of the limitations that there be a "controlled environment" and "anaerobic condition."

By the instant cross-motions, each side seeks summary judgment with regard to RJR's indefiniteness defense.

II. SUMMARY JUDGMENT STANDARD

In a patent case, as in any other type of case, a motion for summary judgment shall be granted if "there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *e.g.*, *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 839 F.2d 1544, 1548 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 828 (1988).

The well-established principles pertinent to such motions can be distilled to a simple statement. The Court may look at the evidence presented in regard to the motion for summary judgment through the non-movant's rose colored glasses, but must view it realistically. After so doing, the essential question is whether a reasonable fact finder could return a verdict for the non-movant or whether the movant would, at trial, be entitled to judgment as a matter of law. *E.g.*, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970).

When parties file cross-motions for summary judgment, each motion is decided separately on the summary judgment standard. *Strauss v. Peninsula*

Reg'l Med. Ctr., 916 F. Supp. 528, 530 (D. Md.) (citations omitted), *aff'd*, 86 F.3d 1152 (4th Cir. 1996).

III. DISCUSSION

Claim 4 of the '649 patent, a claim representative of the claims at issue, states that what is claimed is:

A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising: drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a *controlled environment* and for a time sufficient to substantially prevent the formation of said at least one nitrosamine; wherein said *controlled environment* comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an *anaerobic condition* around the vicinity of said plant portion; and wherein said *controlled environment* is provided by controlling at least one of humidity, temperature, and airflow.

Defs.' Mem. in Supp. of Mo. Summ. J., ex. 5 (the '649 Patent), col. 20, ll. 18-33 (emphases added). As discussed herein, the essential problem with the claims is that no one—certainly not one of ordinary skill in the art—reading the Patents-in-Suit would be able to carry out the invention. That is, the skilled artisan would not be able to know, in advance, whether a particular curing operation would infringe.

The Patents-in-Suit do not teach how to control the environment to prevent an anaerobic condition

that will substantially prevent the formation of a nitrosamine. The only way to ascertain whether a curing operation process would infringe is to examine the result and, if successful in reducing TSNA production, then the operation would have infringed.

A. The Definiteness Requirement

The Patent statute, 35 U.S.C. § 112 (2001), provides in relevant part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The United States Court of Appeals for the Federal Circuit has stated that "[t]he primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx LLC v. Advantage Dental Prods.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002).

A determination that a patent claim is invalid for failure to meet the definiteness requirement of 35

U.S.C. § 112, ¶ 2 is a legal conclusion "that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Commc'ns, L.L.C. v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998). Thus, definiteness is a question of law to be resolved by the court. *See Atmel Corp. v. Info. Storage Devices*, 198 F.3d 1374, 1378 (Fed. Cir. 1999); *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001).

B. Claim Construction

"The first step in any invalidity analysis is claim construction." *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). "Ambiguity, undue breadth, vagueness, and triviality are matters which go to the claim *validity* for failure to comply with 35 U.S.C. § 112 ¶ 2, not to interpretation or construction." *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (emphasis added).

The Federal Circuit does not insist "that claims be plain on their face in order to avoid condemnation for indefiniteness." *Personalized Media Commc'ns*, 161 F.3d at 705. Claims are sufficiently definite if, when read in light of the specification, they reasonably apprise those skilled in the art of the scope of the invention. *Id.*

Star contends that the Federal Circuit has held that a claim that is capable of being construed is necessarily definite, relying upon *Bancorp Services, L.L.C. v. Hartford Life Insurance Co.*, 359 F.3d 1367 (Fed. Cir. 2004). In *Bancorp*, the patent at issue related to a system for administering and tracking the value of life insurance policies in separate accounts. *Id.* at 1369. The district court held that the

claim limitation term “surrender value protection” was not defined in the patent and was not synonymous with “stable value protection,” a term that was used and defined in the specification. *Id.* at 1370. Thus, the district court held that the claims at issue were “fatally indefinite.” *Id.*

On appeal, the Federal Circuit reversed, holding that, in context, “the meaning of the term ‘surrender value protected investment credits’ is reasonably discernible and that the asserted claims of the ‘792 patent are therefore not invalid for indefiniteness.” *Id.* at 1372. As pertinent to the instant discussion, the *Bancorp* court stated:

In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. . . .

We have held that a claim is not indefinite merely because it poses a difficult issue of claim construction; *if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness.* *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1338-39 (Fed. Cir. 2003). That is, if the meaning of the claim is discernible, “even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.” *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

Id. at 1372 (emphases added).

The Court does not read this statement to constitute a holding that the mere fact that a district

court issued a claim construction ruling regarding a term necessarily prevents reaching a conclusion that the term is indefinite. Rather, the issue is whether the claim limitation can be construed so as not to be “insolubly ambiguous” to one skilled in the art.

In the context of an indefiniteness issue, the “construction” of a claim term is the first step - not the final or only step—in the process of determining whether it is sufficiently definite. Furthermore, if the Federal Circuit did have a view that any claim construction by a district court necessarily makes a claim definite, this Court would modify its claim construction decision so as to exclude any construction of the terms at issue.

Accordingly, this Court shall consider whether the claims at issue are indefinite by virtue of the inclusion therein, as limitations, the terms “controlled environment” and “anaerobic condition” as limitations.

C. Terms at Issue

“[T]he determination whether a claim is invalid as indefinite ‘depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.’” *Atmel*, 198 F.3d at 1378 (quoting *North Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993)); accord *Howmedica Osteonics Corp. v. Tranquil Prospects, LTD.*, 401 F.3d 1367, 1371 (Fed. Cir. 2005) (stating that “[t]he definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claim when read in light of the specification”).

“The person of ordinary skill is a hypothetical person who is presumed to be aware of all the

pertinent prior art.” *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (addressing obviousness and citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985)). The “one skilled in the art” analysis for indefiniteness under 35 U.S.C. § 112, ¶ 2 is generally in accordance with similar analyses under § 112, ¶ 1. *See Atmel*, 198 F.3d at 1379-80.

1. “Controlled Environment”

The Court⁵ has construed the term “controlled environment” to mean “controlling one or more of humidity, temperature, and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. MJG-01-1504, Order at 2 [Paper 458] (D. Md. Mar. 31, 2004).

RJR presents a rather persuasive argument that the Patent does not inform those of ordinary skill in the art how to establish the claimed “controlled environment” or how to adjust the humidity, temperature, and airflow relative to each other and to other factors to affect the curing process. Indeed, Star itself seeks to present testimony from an expert witness, Mr. James Sturgill, that is highly supportive of RJR’s position. Thus, the transcript of Sturgill’s deposition includes:

Q: What is the amount of airflow used in conventional barns?

⁵ By Judge Alexander Williams, no relation to the inventor, Jonnie Williams.

A: I don't know that I can give you a number for airflow used in conventional barns.

Q: Well, how the heck do you know where the accused barns have an airflow that was greater than what was conventionally used?

A. That's a good question.

Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 668], ex. 1 (Deposition of James Sturgill) at 111-12.

James Sturgill is likely to be found by the jury to be representative of the hypothetical artisan of ordinary skill. Of course, Star, seeking to avoid summary judgment, takes the position that Sturgill is "an expert on nothing more than barn design, and not representative of one skilled in the art." RJR Mem. in Supp. of Mot. in Limine [Paper 562] at 6 (citing Star's Opp'n to Summ. J. No. 3 [Paper 308] at 22). In the summary judgment context, the Court will assume that a jury would accept Star's position as to Sturgill so that his testimony—while not helpful to Star—would not itself establish indefiniteness.

Essentially, Star takes the position that the "touchstone for proper airflow therefore must be tied to preventing anaerobicity around the plants." Pl.s' Cross-Mo. for Summ. J. [Paper 682] at 9. Thus, Star argues that the definiteness of "controlled environment" can be appreciated only in the context of "anaerobic condition." Therefore, the Court will proceed on the basis that RJR would not be entitled to summary judgment as to the indefiniteness of the term "controlled environment" if the term "anaerobic condition" would pass muster as sufficiently definite.

D. "Anaerobic Condition"

The Court has construed the term "anaerobic condition" to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion exhaust gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. MJG-01-1504, Order at 1-2 [Paper 458] (D. Md. Mar. 31, 2004)

The essential problem is that the term, as construed, does not enable a person of ordinary skill in the art to practice the invention. Rather, the limitation merely states that there must not be an oxygen deficiency sufficient under the circumstances of the particular curing operation to reduce the creation of TSNA's. In sum, one can know that he has practiced the invention only by finding, after a curing operation, that he has obtained a low TSNA reading.

The testimony of the inventor himself establishes that one skilled in the art cannot know, from the patent, how to conduct a curing operation that will achieve the intended result in light of the many variables associated with curing. For example:

Q: So how could one know if its an oxygen deficient condition?

A: If you cure the tobacco and you create an anaerobic situation you'll know it by the levels of the TSNA's that you'll measure.

Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 668], ex. 11 (Deposition of Jonnie Williams) at 50; *see also id.* at 51, 54-57, 61-62.

The indefiniteness issue presented herein is analogous to that presented in *Geneva Pharmaceuticals v. Glaxosmithkline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), in which the court found the term "synergistically effective amount" to be fatally indefinite. *Id.* at 1383. In *Geneva*, as in the instant case, the limitation was defined in terms of the desired result, and there was insufficient guidance to enable the hypothetical artisan to determine the specific action to take without undue experimentation. *Id.* In the instant case, one skilled in the art would not know whether a particular curing operation arrangement was within the claim scope or not except after the fact. And, even when one knew that the result had been obtained so that the invention had been practiced, one could not know how to repeat the success in the next curing run. The *Geneva* court referred to such a claim limitation as "the epitome of indefiniteness." *Id.* at 1384.

In the context of the Patents-in-Suit, the claim limitation "anaerobic condition" may or may not warrant the label of an "epitome of indefiniteness." In any event, the term is fatally indefinite and renders the claims at issue invalid.

III. CONCLUSION

For the foregoing reasons:

1. Defendants' Motion for Summary Judgment of Invalidity Based on Claim Indefiniteness [Paper 668] is GRANTED.
2. Plaintiff's Cross-Motion for Summary Judgment that all the Asserted Claims of the Patents-in-Suit are Not Indefinite [Paper 682] is DENIED.

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3. Judgment shall be entered after decision on the trial of RJR's Inequitable Conduct defense.

SO ORDERED, on Friday, June 22, 2007.

/ s /

Marvin J. Garbis
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

STAR SCIENTIFIC, INC.

Plaintiff

vs.

R.J. REYNOLDS
TOBACCO COMPANY
*et al.*¹

Defendants

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MEMORANDUM AND ORDER

The Court has before it the question of the applicability of the "crime-fraud"² exception³ to the attorney-client privilege with respect to certain alleged improprieties in connection with the procurement of the patents at issue.

I. BACKGROUND

In this case, Plaintiff Star Scientific, Inc. ("Star") has sued Defendant R.J. Reynolds Tobacco

¹ The Defendants are a North Carolina corporation and a New Jersey corporation with the same name.

² To be precise, the seminal opinion on the issue states that the privilege is not applicable to a communication made "for the purpose of committing a crime or tort." *See United States v. United Shoe Mach. Corp.*, 89 F.Supp. 357, 358 (D.Mass. 1950)

³ It is probably more precise to refer to the doctrine as an exclusion from, rather than an exception to, the attorney-client privilege.

Company⁴ ("RJR") for alleged patent infringement. At issue are certain claims of U.S. Patent No. 6,202,649 (the '649 Patent) and its continuation, U.S. Patent No. 6,425,401 (the '401 Patent).

RJR filed a Motion to Compel Production Based Upon the Crime-Fraud Exception to the [Attorney-Client] Privilege [Paper 210]. RJR asserted that Jonnie Williams (the applicant for the patents at issue) and patent counsel failed to disclose material matter to the PTO and misled the PTO with regard to material matters. Judge Williams, to whom the case was then assigned, referred the Motion to Magistrate Judge Day.

As discussed more fully herein, Dr. Harold Burton ("Burton"), wrote a letter dated (and faxed) August 28, 1998 to patent counsel ("the Burton Letter"). The Burton Letter revealed that certain tobacco curing methods formerly used in the United States (and abandoned some thirty years earlier) could produce cured tobacco with TSNA levels that were "undetectable or very low." RJR contended that "Star deliberately withheld the [August 1998] Burton letter from the Patent Office . . . [and that] Star repeatedly represented to the Patent Office that old curing techniques resulted in high TSNA levels, or didn't appreciate or address TSNAs, even though this was contradicted by the Burton letter." Reynold's Opp'n to Star's Objections at 2.

⁴ As reflected in the Memorandum and Order issued November 22, 2004, the Defendants are two corporations with the same name, a North Carolina and New Jersey corporation. For simplicity the Defendants are referred to in the singular as "RJR."

In his Memorandum Opinion Order of May 1, 2003, Magistrate Judge Day found that RJR had presented a *prima facie* case of fraud and that RJR was entitled to certain otherwise privileged documents by virtue of the crime-fraud exception to the attorney-client privilege.

Star objected to the Magistrate Judge's Order. The objection was briefed, but not decided by Judge Williams before the case was reassigned to the undersigned judge. The matter has now been heard by the undersigned Judge.

RJR contended that the Magistrate Judge's finding was sufficient, in and of itself, to warrant the application of the crime-fraud exception. RJR may well have been correct in this argument but, in view of the nature of the issue, the Court decided to undertake an *in camera* review of any "exculpatory" documents that Star may wish to submit as well as certain of the documents at issue. *See* Order of Sept. 27, 2004.

The Court, in deciding to conduct an *in camera* review, relied upon the holding in *United States v. Zolin*, 491 U.S. 554 (1989), which states in pertinent part that:

a lesser evidentiary showing is needed to trigger in camera review than is required ultimately to overcome the privilege.

* * * *

Before engaging in *in camera* review to determine the applicability of the crime-fraud exception, "the judge should require a showing of a factual basis adequate to support a good faith belief by a reasonable person," . . . that *in camera* review of

the materials may reveal evidence to establish the claim that the crime-fraud exception applies.

Id. at 572 (Citations omitted).

The Court, in addition to conducting an in camera review of the documents at issue, has held a hearing in which arguments regarding the applicability of the crime-fraud exception were presented. Further, at the request and expense of RJR, the Court has asked that the Special Master assigned to the instant action examine all documents on the Plaintiff's privilege logs for the purpose of ascertaining which would be relevant to the fraud issues and would be disclosed to RJR if the crime-fraud exception were applied.

As of the date of this Order, the Special Master has not yet completed his documentary examination.⁵ However, the Court has already reviewed and considered such assertedly "exculpatory" materials that Star chose to submit (including declarations of two of the patent attorneys involved) and finds that it is unnecessary to delay the proceeding for the completion of the Special Master's document examination. The evidence already presented, including all purportedly "exculpatory" evidence submitted by Star, establishes, beyond doubt, that it is appropriate to apply the crime-fraud exception in the instant matter.

⁵ There is a considerable volume of materials to be reviewed and certain issues relating to what was to be produced and when.

II. LEGAL FRAMEWORK

The leading case regarding the crime-fraud exception to the attorney-client privilege in a patent case is *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800 (Fed. Cir. 2000).

In *Spalding*, the Federal Circuit determined that the invention record in a patent case "is unique to patent law because the invention record relates to an invention submitted for consideration for possible patent protection" and thus "implicates substantive patent law." *Id.* at 804. Thus, in this matter, the law of the Federal Circuit, rather than that of the Fourth Circuit, shall be applied.

The *Spalding* Court held that "[t]o invoke the crime-fraud exception, a party challenging the attorney-client privilege must make a *prima facie* showing that the communication was made 'in furtherance of a crime or fraud.'" *Id.* at 807 (citations omitted). "Although the party seeking to overcome the attorney-client privilege need not conclusively prove fraud, or necessarily submit direct evidence to make a *prima facie* showing of fraud," a "mere allegation of [fraud, which in this case was the alleged] . . . failure to cite a reference to the PTO will not suffice [to invoke the exception]." *Id.* at 808. Further, the *Spalding* Court determined that inequitable conduct is a "lesser offense than common law fraud" and is not sufficient to render the crime-fraud exception applicable. *Id.* at 807. Finally, the *Spalding* Court determined that:

[common law] fraud is generally held not to exist unless the following indispensable elements are found to be present:

1. A representation of material fact;
2. The falsity of that representation;
3. The intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter);
4. A justifiable reliance on the misrepresentation by the party deceived which induces him to act thereon; and
5. Injury to the party deceived as a result of his reliance on the misrepresentation.

Id.

III. DISCUSSION

RJR has presented evidence at least sufficient to establish a prima facie case of fraud under Spalding so as to warrant the application of the crime-fraud exception to the attorney-client privilege.

With regard to the first two criteria articulated by the *Spalding* Court (requiring a false material representation), RJR has presented evidence from which a fact finder could find it clearly and convincingly established that counsel acting for Williams made false representations of material fact to the PTO.

It is undisputed that, on August 27, 1998, Williams conferred with his then patent attorney⁶ regarding the anticipated efforts to obtain patent protection for an alleged invention. As reflected in the notes of the conference, the patent attorney was told that Burton (not present) would write up a "chemist's explanation" to be faxed to counsel's

⁶ There was more than one attorney involved in the allegedly fraudulent conduct. The Court finds it inappropriate to state the identity of counsel in this decision.

office. Burton, at the request of Williams, did so. Accordingly, on August 28, 1998, counsel received by fax a one page letter of that date, referred to herein as "the Burton Letter."⁷ In pertinent part, the Burton Letter stated:

I was in China for two weeks during 1997 and I was given commercial Chinese cigarettes. I brought some of them back to the US and decided to analyze them for TSNA. To my surprise I could not detect TSNA or when I did they were very low. We analyzed at least five different commercial cigarettes and the [sic] were the leading cigarettes in China. These cigarettes were made of only flue cured tobacco and are more like the cigarettes manufactured in England. China does not import any tobacco and therefore it was all grown in China. Since China is a developing country, they are still use [sic] the old curing technology that was abandoned in the US during the sixties. It seemed to me that the probable cause for the absence of TSNA was the use of the old flue-curing techniques. This technique uses burning fuel and passing the hot gasses through flue pipes in the curing barn. Therefore, tobacco in the old barns were exposed to radiant heat. The modern curing barns are different since the fuel source (propane) is combusted and the exhaust is passed directly

⁷ The Court notes that it is not only the Burton Letter *qua* document but also the pertinent contents identifying prior art consisting of former tobacco curing methods engaged in the United States, that are significant. Thus, even if the Burton Letter were not, in and of itself, prior art, it discloses pertinent prior art known and used by others in the United States. A full copy of the August 1998 Burton letter is attached hereto as Appendix A.

through the tobacco. This can create anaerobic condition [sic] since the oxygen in the atmosphere is depleted by combustion and the combustion gases (carbon dioxide and water) are not aerobic. During curing the tobacco leaf also emits carbon dioxide and will dilute the oxygen further.

The Burton Letter informed Williams and patent counsel that curing techniques that were practiced in the United States and abandoned in the 1960's could produce cigarettes that had TSNA levels that were undetectable or, when detectable, were very low.⁸ Accordingly, in making statements in both the application for, and prosecution of, the patents at issue, Williams' patent counsel was doing so after William's expert had advised that there was a process art known and used by others in the United States that could produce cigarettes with undetectable and low TSNA levels.

Despite this knowledge, on September 15, 1998, patent counsel filed the Provisional Application No. 60/100,372 which stated:

It has been determined that this process [meaning the use of old flue-curing techniques] as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Thus, Williams and his patent counsel were aware that Williams' technical expert stated that a process previously used in the United States to cure domestic tobacco could yield tobacco products with undetectable or low levels of TSNA. The above-

⁸ Even if—as Star's counsel seems to contend—there were a realistic question as to the interpretation of the Burton Letter, there is no doubt whatsoever that a reasonable fact finder could interpret it as has the Court herein.

quoted representation was false and manifestly was material to consideration of whether any patent should issue and, if so, the claims to be allowed.

The fraudulent scheme continued with the filing of the '649 Patent application which claimed priority from the provisional, and which matured into the '649 Patent. Williams and patent counsel continued to fail to inform the PTO that a curing process previously used in the United States by others could yield tobacco with undetectable or very low TSNA levels as the Burton Letter revealed. The '649 application stated:

[T]his process [referring to the old U.S. flue curing process] utilizes primarily radiant heat emanating from the flue pipes to cure the tobacco leaves within the barn. In addition, this process does not appreciate, and does not provide for, controlling the conditions within the barn to achieve prevention or reduction of TSNA's.

Thus, Williams and patent counsel affirmatively led the PTO away from an understanding that the pertinent prior art was not contained exclusively in documents.

Further, in a made statement to the PTO on February 15, 2000, counsel said that "[t]he prior art does not discuss nitrosamine content in cured tobacco" and "does not 'describe[] or suggest[] tobacco products comprising cured tobacco having nitrosamine content reduced by heating uncured tobacco with convection in an environment substantially free of exhaust gases or which otherwise is substantially non-anaerobic.'" By so doing, counsel led the PTO to believe that the pertinent art consisted solely of publications and

provided no hint (much less a candid disclosure) that there was prior art in the form of curing methods previously known and used by others in the United States.

The '401 Patent application was filed on September 25, 2000. Again, the patentee and counsel did not disclose the pertinent information in the Burton letter. In the course of prosecution of the patent, they submitted, together with other materials, a copy of an Interrogatory answer from RJR that contained the assertion that pertinent prior art had not been presented to the patent office. Patent counsel did not, even then, disclose the Burton Letter but, rather, stated that the said documents "are merely cumulative to art already of record." Thus, counsel again was not candid and misled the PTO away from an understanding that the pertinent prior art did not consist solely of documents.

Taking these facts in totality, the Court, guided by *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1359 n.6 (Fed. Cir. 2004) (determining that "[t]he prosecution history is, after all, the record of all correspondence between the patentee and the PTO, and therefore provides the best direct evidence of every representation that the patentee made.) (emphasis in original), finds that the first two criteria for fraud articulated by Spalding are amply established.

"The third element of the alleged fraud, . . . intent to deceive, is the most difficult to prove." *Unitherm*, 375 F.3d at 1360 (Fed. Cir. 2004). The Federal Circuit has concluded, however, that "circumstantial evidence is sufficient to establish the intent element

of common-law fraud.” *Unitherm*, 375 F.3d at 1360 (Fed. Cir. 2004) (citing *Spalding*, 203 F.3d at 807).

Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor. Generally, intent must be inferred from the facts and circumstances surrounding the applicant’s conduct. The drawing of inferences, particularly in respect of an intent-implicating question . . . is peculiarly within the province of the fact finder that observed the witnesses However, given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required While intent to deceive the PTO may be found as a matter of inference from circumstantial evidence, circumstantial evidence cannot indicate merely gross negligence [C]lear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, viz., misleading or deceiving the PTO.

Id. (citing *Molins PLC v. Textron*, 48 F.3d 1172, 1180-1181 (Fed. Cir. 1995)). RJR has submitted ample evidence that a reasonable jury could view as clear and convincing establishing that there was an intent to defraud the PTO.

The Court has considered the assertedly “exculpatory” declarations filed by original and successor patent counsel and finds them by no

means sufficient to negate RJR's *prima facie* case.⁹ Indeed, a reasonable fact finder could well find that the testimony of these patent attorneys (including, but not limited to, the declarations submitted by Star) would support RJR's, rather than Star's, position. In any event, the Court is not presented with the question of whether RJR has proven fraudulent intent on the present record. Instead the Court must decide whether RJR has provided clear and convincing evidence sufficient to establish a fraudulent intent. RJR has done so.

With respect to the fourth criteria, justifiable reliance, there is no doubt that the PTO justifiably relied upon the representations at issue. The best evidence of the PTO's reliance "is that the PTO issued the patent[s]. The statutory pronouncement that 'a patent shall be presumed valid,' 35 U.S.C. § 282 implies that patent examiners are presumed to issue only valid patents." *Unitherm*, 375 F.3d at 1361 (Fed. Cir. 2004) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)). Indeed, the very reason for the duty of candor imposed upon counsel and patent applicants, is to allow the PTO to rely upon their statements. Had evidence of the prior art in the form of curing methods known and used by others in the United States been disclosed to the Examiner, the Court doubts that the patents would have in fact been issued. If this element requires a finding that no

⁹ The Court is not now deciding, and likely will not need to decide, whether RJR has established fraud by clear and convincing evidence. It remains to be seen whether, in light of the evidence at trial, RJR would be entitled to judgment as a matter of law on the issue of inequitable conduct, a "lesser offense" than fraud. *Spalding* at 807.

patent at all would have been issued absent the fraud, then the Court finds that RJR has presented evidence sufficient to make the necessary prima facie case of fraud. If, as this Court believes is more likely, this element requires a finding either that no patent would have issued at all or that the patent(s) that would have been issued would have been materially different from those that were issued, RJR has presented a very substantial case indeed. It seems quite likely that the PTO, if aware of the true facts regarding the prior art, would, at the very least, have narrowed the claims that were allowed.

In regard to the final (reliance) element, RJR has produced evidence sufficient to clearly and convincingly establish injury as a result of reliance. The Federal Circuit has determined that the reliance element:

arises as a matter of course whenever the other four elements are met, because '[a] patent by its very nature is affected with a public interest. The far reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or inequitable conduct and that such monopolies are kept within their legitimate scope. Where fraud is committed, injury to the public through a weakening of the Patent System is manifest.

Unitherm, 375 F.3d at 1361 (Fed. Cir. 2004) (citations omitted).

The Court, in making its determination to apply the crime-fraud exception to the attorney-client privilege, notes that the instant case is not, as in

Spalding, a case involving the mere failure to cite a reference. The *Spalding* Court explained that:

[a] finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct . . . a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission. Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent.

Spalding, 203 F.3d at 807 (Fed. Cir. 2000)(citations omitted). The behavior in question constituted far more than mere "inequitable conduct." Not only was there a pattern of misleading statements, but also the presence of material¹⁰ prior art in the form of

¹⁰ The applicable test for materiality reads in relevant part:

(a) Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section:

* * * *

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with the

curing practices known and used by others in the United States that was hidden was not contained in some publication or reference that one would expect the patent examiner to find. The evidence demonstrates the intent and materiality needed to meet the standard for "the higher threshold of showings" articulated by *Spalding*.

In sum, the Court finds that application of the crime-fraud exception is appropriate.

D. CONCLUSION

For the foregoing reasons:

1. Defendant's Motion to Compel Production Based Upon the Crime-Fraud Exception to the [Attorney-Client] Privilege [Paper 210] is GRANTED.¹¹
2. The Special Master shall continue, and complete, his review of documents as to which Star and/or Williams have asserted an attorney/client privilege.
 - a. All of such documents pertinent to the alleged fraudulent scheme discussed

other information a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the [Patent] Office, or

(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. The Court finds that finds that the prior art known and used by others in the United States as referred to in the August 1998 Burton letter satisfies the materiality requirement of the analysis.

¹¹ In essence, the Court affirms, but modifies, as set forth herein, the Order of the Magistrate Judge.

herein shall be provided to counsel for RJR.

- b. The Special Master shall, forthwith, contact counsel and arrange to provide copies of such documents to counsel for RJR who shall utilize such documents solely for the instant litigation and make no public disclosure without leave of the Court.
 - c. The Special Master shall provide such copies as rapidly as feasible starting 9:00 Monday, December 6, 2004.
 - d. The Special Master promptly shall request any supplemental Orders that may be necessary to enable him expeditiously to complete his work.
3. RJR shall expeditiously proceed with discovery relating to the alleged fraudulent scheme discussed herein, including as necessary, new or additional depositions of persons who have previously refused to provide pertinent responses based upon the attorney-client privilege.

SO ORDERED, on Thursday, December 2, 2004.

/ s /

Marvin J. Garbis
United States District Judge

106a

UNITED STATES COURT OF APPEALS FOR
THE FEDERAL CIRCUIT DISPOSITION
SHEET

...

WEDNESDAY, OCTOBER 22, 2008

11:00 A.M.

...

PETITION FOR REHEARING AND REHEARING
EN BANC

2007-1448 STAR SCIENTIFIC, INC. v. R.J.
REYNOLDS TOBACCO COMPANY (a North
Carolina Corporation), ET AL.

Denied.

....

CONSTITUTION OF THE UNITED STATES

ARTICLE I--THE CONGRESS

Section 8, Clause 8. Patents and Copyrights

[The Congress shall have the power] [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

UNITED STATES CODE**Title 35. Patents****Part III. Patents and Protection of Patent Rights****Chapter 29. Remedies for Infringement of Patent,
and Other Actions****§ 282. Presumption of validity; defenses**

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure—

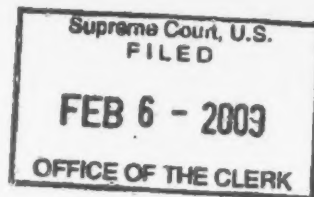
(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

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No. 08-918

IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY,
Petitioner,
v.
STAR SCIENTIFIC, INC.,
Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

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February 6, 2009

* Counsel of Record

QUESTION PRESENTED

Whether the court of appeals correctly applied traditional standards of clear-error review when it concluded that the district court's findings of deceptive intent and materiality were unsupported by the evidence and therefore that respondent engaged in no inequitable conduct.

PARTIES TO THE PROCEEDING

Pursuant to Rule 29.6, Star Scientific, Inc. states that it has no parent company and no publicly traded company owns more than 10% of its stock.

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IN THE
Supreme Court of the United States

No. 08-918

R.J. REYNOLDS TOBACCO COMPANY,
Petitioner,
v.
STAR SCIENTIFIC, INC.,
Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

The case-specific holding of the court of appeals does not warrant this Court's review. It does not implicate any conflict with opinions of other circuits or this Court concerning proof of intent, much less standards of appellate review. And, it manifestly does not raise questions of constitutional significance. Cf. Pet. 16, 30-31.

Rather, the sole issue is whether the record supports a factual finding, by clear and convincing evidence, that the patent applicant intentionally withheld material information during the prosecution of the patents-in-suit so that the patents are unenforceable under the doctrine of inequitable conduct. The district court found inequitable conduct based in large measure on a fanciful theory, advanced repeat-

edly by Petitioner, that four reputable law firms conspired to hide a single document from the Patent and Trademark Office (PTO). The Federal Circuit carefully and thoroughly reviewed the record and concluded that the district court clearly erred, which it did. This disagreement over the significance of the record evidence is inherently case-specific, and will have little, if any, impact on any future case. Accordingly, there is no legal principle for this Court to review, and the petition should be denied.

COUNTERSTATEMENT OF THE CASE

1. Harvested tobacco must be “cured” before it is ready for consumption in tobacco products. Pet. App. 2a-3a. Curing is typically done in barns, in which tobacco leaves are stacked and exposed to heated air, in the form of either the exhaust of burning fuel (a so-called “direct-fired” system) or clean air heated by a separate furnace (an “indirect-fired” system).

The curing process, however, can give rise to tobacco-specific nitrosamines (TSNAs), which, RJR agrees, “may be carcinogenic.” Pet. 4. The inventor of the patents at issue, Jonnie Williams, began exploring methods to eliminate TSNAs in the mid-1990s. Most curing at that time used a direct-fired system. Pet. App. 4a. Williams hypothesized that TSNA formation results from microbial activity on tobacco leaves during curing, and that this microbial activity is promoted by oxygen deficiency in the curing environment. *Id.* Under oxygen-depleted (anaerobic) conditions, microflora on the leaf surface take oxygen from nitrates in the leaves, thereby converting those nitrates into nitrites. Through other chemical reactions, the nitrites then form TSNAs. *Id.*

Williams found that adjustments to heat, humidity, or airflow would substantially prevent the formation of TSNAs. He developed a process—improving on prior indirect-fired systems—for curing tobacco without depleting the environment of oxygen and thereby avoiding the microbial activity which leads to TSNAs. Pet. App. 4a. This process resulted in individual TSNA levels of around 0.05 parts per million, substantially lower than the levels associated with direct- and indirect-fired curing systems. That discovery, which solved a problem that had bedeviled the industry for decades, formed the core of the patents-in-suit.¹ See *id.* at 4a-6a.

2. Four different and respected law firms assisted Williams, and his company Star, at various times during the patent application process and ensuing litigation. This interplay among the firms and Wil-

¹ The patents at issue, U.S. Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent"), address an improved process for curing harvested tobacco leaves to reduce harmful nitrosamines in smoking tobacco. Claim 4 of the '649 patent, which the lower courts found representative of the asserted claims, covers:

A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising:

drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion; and

wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

Pet. App. 9a.

liams formed a principal basis for the district court's finding of inequitable conduct.

a. Star was first represented in prosecuting the patents by Romulo Delmendo, then a senior associate at Sughrue Mion Zinn MacPeak & Seas, and now an Administrative Patent Judge. Williams and Delmendo met in August 1998 to discuss the invention and the application process. Pet. App. 4a. To assist Delmendo in understanding the science of curing and in drafting a patent application, Williams asked Harold Burton, a University of Kentucky researcher, to provide Delmendo with the scientific background of the invention. *Id.* Burton sent Delmendo a one-page letter on the subject. Williams did not review or receive the letter. *Id.* at 4a, 19a.

The Burton letter described Williams's hypothesis connecting TSNA formation to microflora growth and anaerobic conditions, and also stated that Burton had seen low TSNA levels in cigarettes he brought to the United States from China in 1997. Pet. App. 4a-5a, 47a-48a. It went on to speculate that these results might be attributable to "old curing technology that was abandoned in the U.S. during the sixties" but still used in China, including "radiant heat" systems in which pipes filled with hot air radiate heat throughout the barn. *Id.*

Delmendo filed a provisional application with the PTO in September 1998. Pet. App. 5a, 37a. He did not disclose or discuss Burton's speculations about older curing technology in the application because he concluded, after discussing the matter with Burton, that Burton knew little about the older curing technology, and virtually nothing about that technology as practiced in the United States. The application did indicate that some nations, including China, still utilize the radiant-heat method of curing, but stated,

based on Mr. Williams' belief, that "[the radiant-heat] process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA." *Id.* at 5a (alteration in original). This statement was based on an inference made by Williams from information he had received from another tobacco company, indicating that Brazilian tobacco cured using traditional indirect-fired techniques resulted in TSNA levels of 2.0 to 3.0 parts per million. *Id.* at 45a-46a. Prior to filing the provisional Delmendo confirmed the pertinent statement with Burton. Fed. Cir. App'x A217, 218, 226.

After the provisional application had been submitted, Williams later obtained tobacco samples from two farms in the United States, the Jennings and Currin farms, which still used indirect-fired curing methods. Pet. App. 5a-6a. The Jennings sample had been fully cured, and tests showed TSNA levels of 1.5 parts per million, see *id.* at 51a—less than TSNA levels commonly found in tobacco from direct-fired systems but still significantly above the low to undetectable levels produced by Williams's process. *Id.* The Currin sample had been only partially cured, and was microwaved before testing, which prevents TSNA formation; tests of this adulterated sample detected TSNA levels of 0.39 parts per million. *Id.* Williams reported the Jennings data to Delmendo, but did not discuss the less probative Currin data with him. *Id.* at 5a-6a.

In September 1999, Delmendo filed the non-provisional application that later issued as the '649 patent. That application added a disclosure, based on the Jennings data, that:

it is possible to somewhat reduce the TSNA levels by not venting combustive exhaust gases into the curing apparatus or barn. The preferred as-

pects of the present invention are premised on the discovery that other parameters, as identified above (e.g., airflow), can be adjusted to ensure the prevention or reduction of at least one TSNA regardless of the ambient conditions.

Pet. App. 6a-7a (emphasis omitted). Delmendo also removed the statement from the provisional application that "high levels of TSNA" would result from radiant-heat curing of tobacco grown in the United States. *Id.* at 17a n.7.

The non-provisional application was allowed on September 14, 2000. It was ultimately issued as the '649 patent on March 20, 2001. Pet. App. 6a-7a.

b. Shortly after the non-provisional application was filed, Star terminated the Sughrue firm for its patent prosecution work. The undisputed evidence showed that it did so because Star executives saw a Sughrue attorney clash unnecessarily with an examiner at an interview on another application, and because the senior Sughrue partner whom Star originally retained had become gravely ill. Pet. App. 7a, 18a.

Star thereafter retained a new firm, Banner & Witcoff, to handle its patent prosecution work. It also asked a third firm—Paul, Hastings, Janofsky & Walker, with which Star executives had a prior working relationship—to superintend an orderly transition of files from the Sughrue firm to the Banner firm. Pet. App. 7a. Lawyers from the Banner and Sughrue firms met to discuss thoroughly the prosecution. The files, with the Burton letter in them, were then transferred wholesale to the Banner firm. *Id.*

c. On September 25, 2000, soon after the application for the '649 patent was allowed, the Banner firm filed a "continuation application," which later issued

as the '401 patent. The claims of the new application were related to those in the '649 patent but differed from them in certain (and, for purposes here, irrelevant) respects. Pet. App. 8a.

During prosecution of the '401 patent, the Banner firm and Star's litigation counsel, Crowell & Moring, were notified of the Burton letter and the Currin data, which had been disclosed to RJR in litigation over the '649 patent. Attorneys with the Banner firm examined the materials and decided that, particularly in light of other submissions already made to the PTO, they were immaterial. Pet. App. 8a-9a. They therefore did not disclose them to the PTO. The '401 patent was issued on July 30, 2002. *Id.*

3. Star filed suit against RJR for infringement on May 23, 2001, asserting claims under the '649 patent, and alleging that RJR had retrofitted many of its curing facilities, effectively stealing the patent's claimed process without Star's approval. A consolidated complaint to add claims under the '401 patent was filed soon after that patent was issued. RJR defended on several grounds, including that the patents were indefinite and were unenforceable due to inequitable conduct. Pet. App. 8a, 32a-33a.

An inequitable conduct trial was held in January and February of 2005. Some two-and-one-half years later, after pleas to the district court to issue a ruling and ultimately a mandamus petition to the Federal Circuit, the district court found inequitable conduct.² It concluded that, even if the Burton letter and the Currin data were not "*per se*" required to be disclosed,

² The district court also held the patent claims indefinite, and therefore invalid. Pet. App. 88a-89a. The Federal Circuit later reversed that aspect of the judgment, *id.* at 25a-29a, and the petition does not raise that issue here.

the information that other curing methods could produce "low to undetectable levels of TSNA" was material and deliberately concealed from the PTO. Pet. App. 51a, 71a. It specifically found that Star and Williams had switched from the Sughrue firm to the Banner firm, using Paul Hastings as an intermediary, in order to prevent the Banner firm from learning of the Burton letter and "to avoid 'tainting' the Banner firm with Delmendo's knowledge and concerns about disclosures to the PTO." *Id.* at 55a-57a. It rejected Star's explanation for the change, finding some testimony in this regard not credible and simply disregarding other testimony. *Id.* The district court then balanced materiality and intent, and held the patents unenforceable. *Id.* at 75-76a.

b. The Federal Circuit unanimously reversed. It properly stated the governing standard of review—clear error for factual determinations, and abuse of discretion for the determination of inequitable conduct as a whole. Pet. App. 12a. It properly noted that inequitable conduct requires proof by clear and convincing evidence of both materiality and deceptive intent. *Id.* at 13a. And, important here, it properly recognized that, "because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence." *Id.* at 15a.

Applying this standard to the alleged misconduct, the panel concluded that the district court's finding of deceptive intent as to the '649 patent was "clearly erroneous." It recognized that the district court's finding was based in large measure on its acceptance of the "theory that Williams and Star conspired to deliberately prevent Delmendo and his colleagues at the Sughrue firm from disclosing the Burton letter to the PTO by replacing them with the Banner firm and

purposely keeping the Banner firm ignorant of the Burton letter." Pet. App. 17a, 48a. It concluded that this was error because, among other things, there were deficiencies in RJR's proof: "RJR failed to elicit any testimony or submit any other evidence indicating that Star knew what the Burton letter said prior to replacing the Sughrue firm, or that the letter was a reason for changing firms." *Id.* at 19a. Indeed, "RJR admitted at oral argument that it failed even to ask Williams or Star's other executives about these critical facts, and RJR failed to identify any testimony or other evidence when specifically asked by us to do so in supplemental briefing" that the court ordered at oral argument. *Id.*

It likewise found no evidence showing that Star had employed Paul Hastings to "insulat[e]" the Banner lawyers from the Sughrue lawyers, in light of the uncontradicted testimony (which the district court ignored) that lawyers from the Sughrue and Banner firms had met directly. Pet. App. 20-21a. "[T]he Banner firm was clearly given the Burton letter. Yet again, RJR failed to provide clear and convincing evidence to support its allegations." *Id.* at 21a. And, even if Star's explanation for the change in firms were not believed, "it remained *RJR's* burden to prove its allegation regarding the reason for the Sughrue firm's dismissal." *Id.* at 18a. There simply was "no evidence" from which an inference of deceptive intent underlying the change in firms could be drawn. *Id.* at 18a-19a.

Nor did other "facts and inferences relied on by the district court . . . plug this hole in RJR's evidence." Pet. App. 20a. The district court found that Delmendo had "concerns" about the materiality of the Burton letter, but no evidence at trial indicated that he expressed those concerns to Williams, *id.*, and ul-

timately he resolved them, *id.* at 5a. Nor did the statement in the provisional application, concerning TSNA levels in radiant-heat systems, provide clear and convincing evidence of deceptive intent because "provisional applications are not examined" and "the alleged misrepresentation was corrected prior to examination of the non-provisional application." *Id.* at 17a n.7. The panel also noted that, "[t]o the extent the district court also relied on the nondisclosure of the Currin data," the materiality of that data was clearly "questionable" and did not support a finding of deceptive intent as to the '649 patent. *Id.* at 21a n.9.

As for the '401 patent, the panel found the district court's finding of deceptive intent weakened because it "was also heavily based on RJR's 'quarantine' theory." Pet. App. 22a. The panel, however, reversed the district court's holding of inequitable conduct under the materiality prong. It found that the Burton letter and the Currin data were clearly "cumulative" to other references cited to the PTO during the prosecution of the continuation application that resulted in the '401 patent. *Id.* at 23-25a. Based on its holding regarding intent for the '649 patent, and materiality for the '401 patent, the panel reversed the judgment of unenforceability of both patents. *Id.* at 25a.

REASONS FOR DENYING THE PETITION

This intensely fact-bound case does not warrant this Court's review. The petition's claims of an intra- and inter-circuit division, and a conflict with decisions of this Court, are illusory. Even if there were a conflict, it is not implicated here because inequitable conduct could not be found on any standard, given the "major gap[s]" and "hole[s]" in RJR's evidence. Pet. App. 19a-20a. Certiorari should be denied.

I. THERE IS NO INTRA- OR INTER-CIRCUIT DIVISION OF AUTHORITY.

The petition claims that the decision below “departs sharply” from prior opinions of the Federal Circuit, particularly *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006), which, it says, “view the materiality of withheld information as relevant in assessing intent” and “replace[the requirement of actual intent] with a lesser requirement that the applicant merely should have known of the materiality of the withheld reference.” Pet. 18. The decision below is entirely consistent with *Ferring* and similar cases.

1. In *Ferring*, which RJR did not cite below, the Federal Circuit affirmed a grant of summary judgment on the issue of inequitable conduct, concluding that the district court had properly inferred an actual intent to deceive. 437 F.3d at 1194. It based its conclusion on evidence that the withheld information was highly material and that “(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant ha[d] not provided a credible explanation for the withholding.” *Id.* at 1191.

Ferring did not obviate or lessen the requirement that deceptive intent be proven. Cf. Pet. 18. Although the court undoubtedly considered materiality in assessing intent, it did so in conjunction with other circumstantial evidence, including the applicant’s knowledge of materiality and explanation for withholding the material. See 437 F.3d at 1191-94. Certainly it never suggested that materiality alone could suffice to prove intent or that the two issues should be merged. To the contrary, *Ferring* specifically recognized that “materiality does not presume intent, which is a *separate and essential* component of ineq-

uitable conduct.” *Id.* at 1190 (emphasis added; alteration omitted).

Ferring was, in fact, nothing more than a specific application of the commonplace principle that intent may be inferred from circumstantial evidence.³ The decision below in no way departed from that holding. On the contrary, the panel cited *Ferring*, and stated directly (citing *Cargill*, another case relied upon by RJR for the putative intra-circuit split, see Pet. 19) that intent may be inferred from circumstantial evidence. Pet. App. 15a. The court did not “strongly suggest[],” Pet. i, much less hold, that materiality (or knowledge of materiality) cannot or should not be considered in assessing intent. To the contrary, in addressing the district court’s finding of deceptive intent, the materiality of the Burton letter was assumed and the court discussed extensively whether the applicant (the inventor Williams) and others had knowledge of the letter. *E.g.*, Pet. App. 19a (“[A] review of the record shows that Williams actually testified . . . that he had never seen the Burton letter prior to his deposition in the present litigation.”).⁴ That same topic was explored at length at oral argument, and gave rise to supplemental briefs concerning knowledge. Fed. Cir. No. 2007-1448, Dkt. Nos. 45-48. The court of appeals also considered the explanations

³ Indeed, *Ferring* expressly did not articulate any rule extending beyond the specific facts before it. 437 F.3d at 1191. (“We need not in this case attempt to lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant.”).

⁴ In addition, the panel explicitly stated that the applicant’s failure to disclose the Currin data—on which the petitioner also relied for its inequitable conduct claim—could not support the finding of deceptive intent given questions over its materiality. Pet. App. 22a.

offered by the applicant and others for the failure to disclose the letter, and deferred to the district court's credibility determinations. Pet. App. 18a. In short, the panel considered precisely the same factors cited in *Ferring* (and other decisions cited by petitioner⁵), and simply arrived at a different conclusion, which was compelled by the record in this specific case.

Having determined that the district court clearly erred in concluding that RJR had proved a threshold level of intent, the panel properly reversed the finding of inequitable conduct without separately addressing the materiality of the information. The petition repeatedly notes that the panel "did not dispute" the materiality of the information, e.g., Pet. 16-17, 21, 34, the implication being that the Federal Circuit believed materiality irrelevant, or failed to address materiality when it ought to have done so. The former is mistaken, for the reasons just set forth. And the latter is no basis for certiorari, and is mistaken in any event. In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, the Federal Circuit explained that it was "unnecessary to discuss materiality" when the district court's finding of intent was clearly erroneous. 863 F.2d 867, 872 n.5 (Fed. Cir. 1988).

2. The petition also argues that "[o]ther Federal Circuit decisions conflict with the decision below by permitting the consideration of materiality as evidence of intent, even where actual intent continues to be required." Pet. 19. Again, this seeks to manufacture a conflict where none exists.

⁵ Pet. 19; see *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1315-18 (Fed. Cir. 2008); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1365-67 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366-68 (Fed. Cir. 2007).

The petition's reliance on *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000), is misplaced. Pet. 19. The excerpt it cites from *Li* merely states the unexceptional proposition that *once* threshold levels of materiality and intent have been established by clear and convincing evidence, these must be weighed by the district court to determine if the equities warrant a finding of inequitable conduct. 231 F.3d at 1378. Other cases cited by the petition say nothing any different,⁶ and the court below specifically reaffirmed this basic rule. Pet. App. 13a. Because RJR failed even to make the necessary threshold showing of intent, however, the panel properly held that it had no cause to review whether the district court abused its discretion when it balanced the equities. *Id.* at 13a, 16a, 19a; see also *id.* at 39a (district court recognizing the need for such a threshold showing). This record-specific question does not merit further review.

Petitioner fares no better with the remaining cases it cites. In each of these highly fact-bound decisions, intent was inferred from extensive circumstantial evidence. See *Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239-42 (Fed. Cir. 2003); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1344-49 (Fed. Cir. 2008). In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, for example, it was "the overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure" that supported the finding of deceptive intent. 487 F.3d 897,

⁶ See Pet. 19-20 (citing, among other cases, *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007) ("The more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find inequitable conduct.")).

919 (Fed. Cir. 2007). Intent was not inferred merely from "[t]he high materiality of the withheld prior art coupled with the lack of a credible explanation for the nondisclosure," as petitioner selectively quotes from that decision. Pet. 20 (alteration in original). The decision below states no legal rule that remotely constitutes a conflict with these cases.

The petition's reliance on decisions in which counsel offered "no credible explanation" for their action is particularly inapt here. At trial, multiple lawyers from the two patent firms testified at length regarding their assessment of the Burton letter and their reasons for not disclosing it to the PTO. See *infra* at 18. The district court ignored that reasoned testimony, and instead fashioned an alternative theory which, as the court of appeals properly recognized, had no basis in evidence. Pet. App. 17a-21a.

3. There is likewise no division between the opinion below and decisions of other circuits, much less a "stark and longstanding circuit split." Pet. 21-23.

The most recent circuit case identified in the petition was decided 28 years ago,⁷ and the currency of these decisions is doubtful. None of them has been cited in support of a "gross negligence" standard since the Federal Circuit's 1988 *en banc* opinion in *Kingsdown*, which held that inequitable conduct cannot be inferred from grossly negligent behavior. 863 F.2d at 876. The Eighth Circuit, indeed, recently characterized *Kingsdown* as having "resolv[ed] conflicting precedent pertaining to gross negligence and intent," see *Schinzing v. Mid-States Stainless, Inc.*,

⁷ See Pet. 22-23 (citing *Digital Equip. Corp. v. Diamond*, 653 F.2d 701 (1st Cir. 1981); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495 (10th Cir. 1979); *Int'l Tel. & Tel. Corp. v. Raychem Corp.*, 538 F.2d 453 (1st Cir. 1976)).

415 F.3d 807, 813 (8th Cir. 2005), and applied the *Kingsdown* standard without reference to an arguably contrary pre-1988 Eighth Circuit case addressing patent invalidity based on allegations of “gross negligence,” see *E.I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1268-70 (8th Cir. 1980). District courts in these circuits have consistently applied *Kingsdown* without referring to these older decisions or suggesting the existence of a circuit split. *E.g.*, *Applera Corp. v. MJ Research Inc.*, 372 F. Supp. 2d 221, 225 (D. Conn. 2005); *Mitek Surg. Prods., Inc. v. Arthrex, Inc.*, 21 F. Supp. 2d 1309, 1317 (D. Utah 1998), *aff’d*, 230 F.3d 1383 (Fed. Cir. 2000) (table). And, PTO regulations dealing with fraud and the duty of candor—which were relied upon in several of the pre-1988 circuit decisions, *e.g.*, *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 707 (1st Cir. 1981)—have since been amended to remove references to “gross negligence” in order to conform to *Kingsdown*. Notice of Final Rulemaking, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992); Notice of Proposed Rulemaking, 56 Fed. Reg. 37321, 37323 (Aug. 6, 1991).

The supposed “sharp and irreconcilable split” over this issue, if ever it existed, is stale. Notably, this Court has denied three prior petitions—including one from the decision in *Kingsdown*—raising this same issue. See Petition for Writ of Certiorari at 19-23, 28-31, *Nilssen v. Osram-Sylvania, Inc.*, 128 S. Ct. 2938 (2008) (No. 07-1293) (arguing that *Kingsdown* represented a departure from “a series of decisions in the 1970s and 1980s from the regional circuits and then the Federal Circuit”); Petition for Writ of Certiorari at 20-22, 24-25, *Ferring B.V. v. Barr Labs., Inc.*, 549 U.S. 1015 (2006) (No. 06-372) (alleging “a three-way regional circuit split on the showing of ‘intent’ necessary to trigger an inequitable conduct holding”); Peti-

tion for Writ of Certiorari at 24-26, *Hollister Inc. v. Kingsdown Med. Consultants, Ltd.*, 490 U.S. 1067 (1989) (No. 88-1562) ("The *in banc* Court simply overrules that entire prior body of law holding that intent to deceive may be found from the presence of gross negligence alone . . ."). Nothing in the petition in this case provides any reason not to follow this same course here. In the highly unlikely event that one of the regional courts of appeals decided this issue in conflict with the Federal Circuit, that would be the case that might warrant review.

4. Even if there were "confusion" regarding inequitable conduct within the Federal Circuit, Pet. 21, this case would present a particularly poor vehicle for considering it. This is because there was no inequitable conduct here under any standard. The district court based its finding of deceptive intent with respect to the '641 patent on three principal facts: (i) non-disclosure of the Burton letter, (ii) statements in the provisional application that radiant-heat systems in the United States yield high levels of TSNA's, and (iii) the purported conspiracy to change law firms to avoid disclosure of material information. See Pet. App. 46a-53a. But nothing in the record shows that Williams or others at Star were aware of the specific contents of the Burton letter or should have known to disclose it; the relevant statements in the provisional application were not considered by the PTO and, in any event, were clearly corrected in the non-provisional application; and all files held by the Sughrue firm were transferred to the Banner firm, with no evidence of an attempt to conceal anything. *Id.* at 17a-21a. The Federal Circuit was simply correct that the ultimate finding of deceptive intent was "clearly erroneous."

This is true even under the "should have known" standard advocated by RJR. See Pet. 18-19. Under any standard, there still must be proof that the patent applicant *knew* of the purportedly material information during the prosecution process. See *id.* at 18-21. But there was no evidence that Williams or others at Star knew of the specific contents of the Burton letter, as the Federal Circuit properly concluded after extensive and supplemental briefing on this question. Pet. App. 19a. Furthermore, *Ferring* itself recognizes that there is no inequitable conduct when an applicant presents a "credible explanation" why information was not disclosed. 437 F.3d at 1191; Pet. 18 (recognizing same). There was extensive testimony, all of which the district court ignored, about why Star's patent counsel determined that it was unnecessary to disclose the Burton letter and the Currin data. Pet. App. 5a, 6a, 8a-9a; Star Scientific Fed. Cir. Br. 28-29, 33-35, 38-39, 45-47; Fed. Cir. App'x A219, 224-25, 239, 240, 242, 253-54, 258, 264, 374, 378-80, 537-38.

And, most fundamentally, the information that RJR believes should have been disclosed here was utterly immaterial. The Burton letter contained uninformed speculation about Chinese tobacco, which would typically have been cured in a fashion significantly different from the "controlled conditions" that are at the heart of the patents-in-suit. Burton himself candidly testified at trial that he "d[id]n't have an idea" what TSNA levels in the United States would have resulted from curing with these now-abandoned methods. Fed. Cir. App'x A351; *see also id.* at A254, 518-19, 523, 533, 537-38.; Star Scientific Fed. Cir. Br. 27-30. As for the Currin data, both the district court and the panel expressly questioned the materiality of this information because the sample was not fully

cured and was then microwaved before testing, see Pet. App. 5a-6a, 21a n.9, precluding reliance on that information as proof of deceptive intent even under the petitioner's standard. The panel did not leave "undisturbed" the district court's findings concerning materiality, Pet. 13; it simply passed over these fact-bound and record-intensive determinations as unnecessary to its decision, see Pet. App. 18a n.8. There is no good reason for this Court to address these issues in the first instance.⁸

II. THERE IS NO CONFLICT WITH ANY DECISION OF THIS COURT.

Petitioner additionally claims a conflict with decisions of this Court regarding the use of circumstantial evidence, and indeed even the proper role of appellate courts. The decision below, however, nowhere purported to impose any limit on the consideration of circumstantial evidence, nor did it modify traditional principles of appellate review.

1. Far from rejecting circumstantial evidence as competent proof, see Pet. 23-25, the panel directly and explicitly acknowledged that such evidence may be relied upon in fact-finding: "because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial

⁸ The petition also challenges the determination that the Burton letter and Currin data were cumulative of other information disclosed during prosecution of the '401 patent, and therefore were not "material." See Pet. 34-35. However, it offers no support for its suggestion that the disclosed information should be ignored merely because it was submitted later in the patent prosecution process, and provides no basis for overturning the panel's conclusion.

evidence." Pet. App. 15a.⁹ Moreover, it went on to assess the circumstantial evidence from which the district court inferred improper intent. *Id.* at 17a-22a. Nowhere did it suggest, much less hold, that district courts may not infer intent from such evidence. The petition recognizes as much; whatever the Federal Circuit purportedly did wrong, the petition acknowledges that it did it "*sub silentio*." Pet. 24. The Federal Circuit's conclusion that the inference drawn by the district court in this particular case was clearly erroneous is error-correction that does not warrant this Court's attention.

The cases cited in the petition concerning circumstantial evidence are irrelevant. They arose in the criminal context, and involved such unrelated issues as proof of guilt, see *Holland v. United States*, 348 U.S. 121 (1954), the admission of extrinsic-act evidence, see *Huddleston v. United States*, 485 U.S. 681 (1988), and discrimination in jury selection, see *Miller-El v. Cockrell*, 537 U.S. 322 (2003). The factual analyses in those cases were based on the unique records at issue, and do not remotely cast doubt on the decision here. *E.g., id.* at 347 (concluding based on the record that the trial court committed "clear error" in its findings). That petitioner would even try to analogize this case to the due process decision in *Jackson v. Virginia*, 443 U.S. 307 (1979), or the equal protection holding in *Batson v. Kentucky*, 476 U.S. 79

⁹ See also Pet. App. 19a ("As noted earlier, the district court may infer facts supporting an intent to deceive from indirect evidence. *Cargill*, 476 F.3d at 1364. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR's lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.").

(1986), is itself ample proof that there is no real conflict.

2. Equally baseless is petitioner's claim that "[t]he Federal Circuit . . . ignored this Court's admonitions about the proper role of appellate courts in reviewing trial court factfinding." Pet. 25. The Federal Circuit recited the proper "clear error" standard of review, see Pet. App. 12a ("we review . . . factual determinations for clear error"), and applied that standard consistently, see *id.* at 18a ("credibility determinations are an aspect of fact-finding that appellate courts should rarely reverse").¹⁰ The petition identifies no relevant misinterpretation or misstatement of law. It criticizes the Federal Circuit for not quoting the "any rational trier of fact" due process standard from *Jackson*, see Pet. 25, but neither explains how the *Jackson* formulation differs from the clear-error standard stated by the panel or, more importantly, why the Federal Circuit was required to cite *Jackson*, particularly when prior cases from this Court—and petitioner's own brief below—address that standard without reference to *Jackson*. *E.g.*, *Anderson v. City of Bessemer City*, 470 U.S. 564, 573-76 (1985).

In sum, the petition raises only a disagreement with the appellate court's analysis of the record, see Pet. 25-27, including supposed errors of omission, *e.g.*, *id.* at 26 ("the Federal Circuit did not even acknowledge the trial court's explicit rationale"). But such a fact-laden dispute simply does not implicate

¹⁰ Far from having given "no deference to the . . . credibility judgments by the trial judge," specifically concerning "inventor Williams," Pet. 26, the panel expressly accepted the district court's assessment of Williams's credibility for purposes of analysis, Pet. App. 18a-19a.

“the proper role of appellate courts.” *Id.* at 25. Even if the court of appeals’ analysis were not absolutely correct—and it is—the correction of “erroneous factual findings” or the “misapplication of a properly stated principle of law” is not a proper basis for certiorari. Sup. Ct. R. 10.

3. Petitioner also argues that review is warranted to reaffirm that “well-established principles governing appellate review of trial court factfinding” govern patent cases and “to make clear that there are no special limitations upon the trial court’s assessment of circumstantial evidence of intent applicable to inequitable conduct or to patent cases.” Pet. 27, 29-30. No such clarification is necessary. The Federal Circuit did not hold that clear-error review applies differently in patent cases or that any “special limitations” restrict consideration of circumstantial evidence in patent cases. To the contrary, it cited traditional principles of appellate review and standards for assessing circumstantial evidence. See Pet. App. 12a, 18a. That the petitioner disagrees with the court’s conclusions, and its reading of the factual record, does not constitute a “conflict” worthy of review.

Petitioner cites various patent cases in support of this supposed conflict, none of which is at odds with the decision below. Pet. 27-29. The questions presented in both *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), concerned whether the Federal Circuit had properly defined the relevant legal standard for, respectively, an award of injunctive relief and a finding of “obviousness.” 547 U.S. at 391-93; 127 S. Ct. at 1742-43. *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machine Co.* was part of the early line of cases first recognizing the defense of inequitable conduct and defin-

ing the bounds of the doctrine; the facts of the case were considered as a necessary incident to discussion of the legal standard. 324 U.S. 806, 814-19 (1945). At issue in *Zenith Radio Corp. v. Hazeltine Research, Inc.*, was whether an individual may be bound by a prior judgment in litigation to which the individual was not a party; only after addressing this legal issue did the Court review the lower courts' assessments of the factual record. 395 U.S. 100, 108-12 (1969). And, finally, in *Dennison Manufacturing Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), this Court granted the petition and vacated the judgment not because the court of appeals had "substitut[ed] its view of factual issues for that of the District Court," Pet. 29 (alteration in original), but because the Federal Circuit had not addressed the unresolved question of the proper standard of review. 475 U.S. at 811. No such issue of law is presented here.

The petition also suggests that this case necessarily implicates important federal questions and warrants review because it concerns the issuance and validity of a patent—an issue supposedly "of constitutional dimension." Pet. 30-32. This is clear overreaching. Not every patent case merits this Court's review, nor does every party's disagreement with factual findings concerning patent litigation justify certiorari. A patent case, like any other, warrants review by this Court only if it reflects a split of authority, conflicts with decisions of this Court, or presents an issue of exceptional importance to the administration of federal law. This case satisfies none of these standards. It turns on nothing more than that "RJR failed to carry its burden of proof." Pet. App. 20a; see also *id.* at 19a, 21a.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

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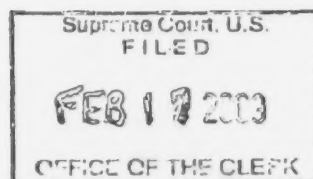
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No. 08-918

IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY,
Petitioner,

v.

STAR SCIENTIFIC, INC.,
Respondent.

*On Petition for a Writ of Certiorari to the United
States Court of Appeals for the Federal Circuit*

REPLY FOR PETITIONER

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REPLY FOR PETITIONER

The Petition for Certiorari demonstrates that the Federal Circuit reversed the district court by attacking a straw man, and by completely ignoring the district court's actual reasoning. Citing almost exclusively to the Federal Circuit decision, the Brief in Opposition now argues against certiorari by again misstating the actual reasoning of the district court, just as the Federal Circuit did. Opp. 8.

The concluding section of the trial court's opinion, Pet. App. 70a-76a, explains its reasons for finding inequitable conduct based on a consistent pattern of actions taken over an extended period:

There is no doubt that throughout the process of prosecution of the Patents-in-Suit, Williams and others kept critical information from the PTO so as to give the false impression that, as of the time of the application leading to the Patents-in-Suit, there had been no curing processes used in the United States that was capable of producing tobacco with low levels of TSNA.

Pet. App. 71a; *id.* at 72a-73a (summarizing actions taken). As discussed at length in the petition, Pet. 6-12, 32-34, the district court's conclusion was fully supported by evidence and specific findings concerning Williams' knowledge of highly material information,¹ and the various acts and omissions by which

¹ Williams admitted knowing no later than September 15, 1998—the date on which false statements were submitted in the provisional '649 application—that long-used curing methods in the United States could produce low or undetectable TSNA levels. App. A290. Indeed, Star's trial counsel in closing

he and others kept that information from the PTO.² It was also supported by several very significant credibility findings, likewise ignored by the Federal Circuit, on the basis of which the trial court ex-

told the court that "everyone involved" in pursuing the patent knew that "[y]ou can get undetectable TSNA's" with existing methods, App. A422, and the trial court so found, Pet. App. 71a.

Notwithstanding these clear admissions, Star and the Federal Circuit focus narrowly on whether the Burton letter itself should have been disclosed. Pet. App. 17a-19a; Opp. 8-9, 12, 15. This singular focus ignores the district court's finding that the critical non-disclosure was not the Burton letter, but "the essential fact" that existing curing methods could produce tobacco with low TSNA's. Pet. App. 71a. Thus, while Star was wrong in denying the existence of any evidence showing that Williams was aware of the Burton letter, Opp. 17; *see* Pet. 6 (testimony cited), that denial also misses the point.

² The Petition summarizes the ample record evidence showing that Williams, among other things, (a) misstated the facts about this prior art to his own counsel, Pet. 6-7; (b) caused the provisional application for the '649 patent to include a false statement about the TSNA levels resulting from existing methods, Pet. 7; (c) caused the non-provisional application for the '649 patent to omit reference to the low TSNA levels produced despite referencing the very prior art techniques in question, Pet. 7-8; and (d) failed to disclose the same facts in a variety of other instances when he should have done so, including in a "Petition to Make Special," which carries a heightened disclosure obligation, Pet. 8-9, in a personal interview with the patent examiner, Pet. 9, and throughout the prosecution of the related '401 patent, Pet. 9-10.

pressly discounted testimony offered to justify the failure to disclose the information.³

Rather than attacking the trial court's reliance on a pattern of actions taken over a period of four years that denied the PTO highly material information, the panel wrongly asserted that the deceptive intent finding was "based primarily on" Star's decision to change legal counsel during the patent prosecution. Pet. App. 17a. Though the trial court opinion mentioned this episode only in discussing background facts, *id.* at 54a, and not in its statement of reasons for its ruling, *id.* at 70a-76a, to the Federal Circuit this was the critical basis for district court's ruling. It thus reversed the finding of deceptive intent, based on its finding of insufficient evidence to show that the law firm switch was made in order to conceal the Burton letter. *Id.* at 21a.

³ The Opposition asserts that the district court ignored testimony supporting Star's decision not to disclose the Burton letter. Opp. 15, 18. To the contrary, the trial court concluded that there was "no valid justification for failing to make the disclosure," Pet. App. 68a, and stated its reasons for rejecting the contrary testimony of Star's witnesses. The trial court found "substantial doubt as to the professional independence" of the patent lawyers involved in the decision, because they were biased by the promise of stock-options to be received only if the patent issued. *Id.* at 70a. It also found suspect the testimony of Star's lead trial lawyer, McMillan, who would receive a substantial contingent fee depending on the outcome of the case. *Id.* at 70a n.16. The district court also discounted the testimony of Dr. Burton, because Star had endowed an academic chair in his name, "paid him a retainer more than his annual salary regardless of any work product produced, and gave Burton hundreds of thousands of dollars in stock options." *Id.* at 69a. The court below mentioned none of this.

In addition to wholly ignoring the trial court's actual reasoning, the court below expatiated on the "need to strictly enforce the burden of proof" of inequitable conduct by clear and convincing evidence "because the penalty for inequitable conduct is so severe," and to "be vigilant in not permitting the defense to be applied too lightly." Pet. App. 13a-14a. It also discussed at length the proposition that materiality and intent are separate requirements that must each be proven separately. *Id.* at 14a-15a.

It thus appears that the panel deliberately gave no weight at all to the trial court's central reliance on the materiality of undisclosed information and its concealment for four years. In doing so, the decision exemplifies an ongoing division within the Federal Circuit on precisely that issue. As shown in the petition, Pet. 18-23, and acknowledged by Star, Opp. 11-13, the predominant view expressed in the circuit's decisions has been that materiality of withheld information is relevant evidence of intent. By treating the trial court's actual reasoning as irrelevant—even unworthy of mention in this case—the panel applied the formerly dissenting approach of some of the court's judges. It also contravened settled authority from this Court regarding the proper roles of fact-finders and appellate courts.

I. THE DECISION BELOW IS SHARPLY AT ODDS WITH MOST DECISIONS OF THE FEDERAL CIRCUIT AND THOSE OF OTHER CIRCUITS ADDRESSING PROOF OF INTENT IN INEQUITABLE CONDUCT

1. Star concedes that Federal Circuit decisions have "considered materiality in assessing intent," Opp. 11, as "a specific application of the common-

place principle that intent may be inferred from circumstantial evidence,” Opp. 12. Star also acknowledges that the Federal Circuit has even held that materiality may reduce the required showing from actual intent to a mere “should have known” standard. Opp. 11. *See, e.g., Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-15, 1318 (Fed. Cir. 2008). This “should have known” standard sharply contrasts with the Federal Circuit’s analysis in this case. Pet. 16-21.

Star’s assertion that the decision below is nothing new rests on a futile claim that the panel actually gave weight to the trial court’s reasoning based on the materiality of the information concealed. Opp. 12-13. A brief review of the decision shows this is plainly false.

The trial court focused on the fact that Williams was concededly well aware that prior curing methods were “capable of producing low-TSNA tobacco.” Pet. App. 72a. It found that known information to be “manifestly material” because the alleged invention was itself aimed at consistently achieving precisely that goal. *Id.*⁴ The trial court then found that Reynolds had proved intent to deceive, because Williams and others had “engaged in a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco.” *Id.* The district

⁴ This information would be of obvious interest to the PTO because, as Star has acknowledged, at the time of the patent prosecution, “relatively little was known about specific TSNA levels achievable with other curing methods.” Star Opening Brief at 14, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008) (No. 2007-1448).

court thus noted a pattern of conduct, running from an express falsehood submitted to the PTO on Williams' direction in September 1998, through issuance of the '401 patent in July 2002, *id.* at 72a-75a. This chain of events supported a finding of deceptive intent precisely because it is unreasonable to suppose such obviously material information could have been withheld for so long by accident, without deceptive intent.

Star appears to argue that because the Federal Circuit did not reverse the trial court's finding of materiality, it necessarily evaluated the relevance of materiality in its decision. Opp. 13. But the panel made no reference at all to the trial court's actual reasoning, and certainly offered no reason to doubt its validity. Rather, the Federal Circuit discussed extensively the general obstacles standing in the way of an inequitable conduct finding in any case, including the need for separate findings of both intent and materiality. Pet. App. 13a-16a. It then reversed after a detailed discussion focusing solely on the change of law firms. *Id.* at 17a-22a.

In thus giving no weight as evidence of intent to the fact that highly material information was withheld for a long time, the panel follows several opinions of individual Federal Circuit judges who objected to "[m]erging intent and materiality" by considering the latter to be evidence of the former. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting); *see also, e.g., Ferring*, 437 F.3d at 1196 (Newman, J., dissenting). Application of this blindered approach in the future would make proof of

deceptive intent exceedingly difficult in any but the most obvious cases.

2. Star does not deny that regional courts of appeals have held, contrary to the Federal Circuit, that actual intent to deceive is not even a required element of inequitable conduct. *See, e.g., Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 709 (1st Cir. 1981); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495, 501, 504-05 (10th Cir. 1979). It attempts to diminish the significance of this circuit split by claiming that current Federal Circuit authority has effectively abrogated these precedents. Opp. 15-16.

However, this Court has recently affirmed the continuing relevance of regional circuit precedent in some cases including patent claims. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002). And Justice Stevens noted that these regional circuit cases involving patent issues can give rise to circuit splits warranting this Court's review. *Id.* at 839 (Stevens, J., concurring in part and in the judgment).

That fact is not undermined by Star's citation of district court decisions applying the Federal Circuit intent rule. Opp. 16. These cases were all appealable to the Federal Circuit and therefore governed by Federal Circuit law. Thus, they say nothing about the standards governing district court cases where patent issues arise in counterclaims under *Holmes Group*.⁵

⁵ Star's argument, Opp. 16-17, that this Court has denied previous petitions for certiorari raising this inter-circuit split is also unavailing. First, this case presents not only a stark inter-circuit split, but also a deep division over the standards govern-

Finally, Star's argument that "there was no inequitable conduct here under any standard," Opp. 17, again rests upon Star's fundamental mischaracterization of this case. Star falsely asserts that the district court's finding of intent was predicated on three discrete facts, not the wide ranging pattern of conduct over a period of years upon which the district court actually relied. Moreover, Star's argument that the information withheld was in fact immaterial, even though the court below left standing the materiality finding, is patently false. Try as Star does to characterize the withheld information as a single letter, the trial court made clear that the concealment was of the "essential fact" that existing curing methods were capable of "the production of tobacco with low to undetectable levels of TSNA"—the precise objective of Williams' purported invention. Pet. App. 71a; *see supra* note 1.

II. THE FEDERAL CIRCUIT HAS VIOLATED THIS COURT'S PRECEDENTS ON APPELLATE REVIEW OF TRIAL COURT FACTFINDING

1. By reversing the trial court's holding of deceptive intent without mentioning it or offering any rea-

ing the intent inquiry within the Federal Circuit that had not yet ripened when those petitions were filed. Second, the practical importance of the circuit split is far greater now that the Federal Circuit has applied its own approach to the intent inquiry in an extreme and unjustified manner that would contravene basic principles of trial court factfinding and appellate review, as discussed more fully in the next section.

son to doubt its soundness, the Federal Circuit flagrantly violated this Court's directives about appellate review of factfinding. Star's only response is to claim that the panel actually considered the trial court's reasoning, including the materiality of the withheld information. Opp. 19-20. This claim is plainly false.

Star notes the statement of the panel that "intent can be inferred from indirect and circumstantial evidence," and baldly asserts that the court "went on to assess the circumstantial evidence from which the district court inferred improper intent. [Pet. App.] at 17a-22a." Opp. 19-20. While the court did give lip service to the relevance of circumstantial evidence, it most assuredly did not consider or even mention the evidence or inferential reasoning on which the trial court actually relied.

All of the discussion leading to reversal of the finding of deceptive intent focused on the change-of-law-firm incident. The referenced section begins with the assertion that the trial court's intent finding "was based primarily on" that incident. Pet. App. 17a. After four pages devoted solely to that subject, the court held the intent finding clearly erroneous, "[g]iven the heavy reliance by the district court on the . . . [law firm] 'quarantine' theory [and] the numerous evidentiary failings relating to this theory." *Id.* at 21a.

The gist of the Federal Circuit's reasoning is that there was inadequate proof of a conspiracy to switch law firms for the purpose of concealing the Burton letter, and, *on that basis*, the deceptive intent finding was erroneous. Following the court's admonitions about the need for separate consideration of

materiality and intent, Pet. App. 13a-16a, there is no mention anywhere in the opinion of the simple inference on which the trial court rested: That Williams and others knew early on that prior art methods could achieve very low TSNA tobacco—the very goal of their invention—yet never over several years disclosed that highly material fact to the PTO.

Star's only other response is to dismiss this Court's cases as irrelevant because they did not occur in the patent context. Opp. 20-21. This distinction flies in the face of this Court's repeated warnings, Pet. 27-30, that ordinary principles of this Court's jurisprudence cannot be discarded in the patent context without some valid rationale. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

In any event, this Court has applied the same principles regarding circumstantial evidence in the inequitable conduct context. Pet. 28-29. Star dismisses *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814-19 (1945), in a single, vaguely worded sentence noting that it was an "early" case, and that the discussion of the facts was "a necessary incident to discussion of the legal standard." Opp. 22-23. Whatever that may mean, it does not change the fact that *Precision Instrument* found the evidence in that case sufficient to show inequitable conduct using ordinary inferences from the totality of the facts.

Star's dismissals of *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), and *Dennison Manufacturing Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), are similarly terse and devoid of reasoned argument. Opp. 23. Star does not dispute the relevant fact about both cases—that this

Court applied the same principles that Star dismisses as irrelevant to the patent-law context.

2. Star also offers no basis to contest that the panel below contravened this Court's precedents regarding the appellate review of factfinding. Star says only that the panel alluded to the clear error standard of review and purported to apply it. Opp. 21. But for all of the reasons set forth above, and in the petition, Pet. 25-27, the court's blatant refusal to acknowledge the actual reasoning of the trial court renders its application of the clear error standard a sham. It is simply impossible that the Federal Circuit paid proper deference to factual findings that it did not even mention or show any reason to question.

3. Finally, Star offers virtually no response to Reynolds' showing that the issues in this case are of great importance and urgency, warranting this Court's review. Pet. 30-32. Star merely argues that the constitutional foundation for the patent system is irrelevant because "[n]ot every patent case merits this Court's review." Opp. 23. Reynolds showed, however, that this case warrants review not simply because it is a patent case, but because it announced an approach that will have far-reaching and grave ramifications for the patent system, and will undermine the constitutional bedrock upon which the patent system rests. If courts in future cases follow the example of the Federal Circuit in denying any consideration to the materiality of undisclosed information—and the panel's soliloquy on the need to keep materiality and intent separate may well cause them to do so—then patents will routinely be permitted to issue in the face of deception, nondisclosure, and

other misconduct by patent applicants. Such a serious threat to the operation of the patent system plainly warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

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